09/745737

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
7175-64836		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US99/17877	06 AUGUST 1999	07 AUGUST 1998
International Patent Classification (IPC) or national classification and IPC IPC(7):A 61F 13/00 and US Cl.: 604/304		
Applicant HENLEY, ALAN WAYNE		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28 JANUARY 2000	11 OCTOBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer KIM MARIE LEWIS
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1191

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/17877

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-25 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims:
pages 26-31 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings:
pages 1-21 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/17877

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Inventive Step (IS)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Industrial Applicability (IA)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO

2. citations and explanations (Rule 70.7)

Claims 1, 17, 36 and 38 lack novelty under PCT Article 33(2) as being anticipated by Westaby et al. Claims 1, 17, and 36 Westaby et al. anticipates a wound irrigation device comprising a bandage configured to cover a wound (10) and to seal about the perimeter and providing a cavity over the wound, a fluid supply and a fluid drainage and fluid delivery and fluid drainage tubing.

Claim 38, although not stated it is inherent in the disclosure that a receptacle of some sort is connected to the fluid drainage line in order to collect the fluid drained from the wound.

Claims 3, 12-15, 21, 22, 37 and 39 lack an inventive step under PCT Article 33(3) as being obvious over Westby et al. Claims 3 and 37, Westaby et al. teach that hydrogen peroxide may be supplied to wound. Westaby et al. fail to teach a liquid medication pump is coupled to the fluid supply. The examiner contends that the addition of medication to a patient intravenously or directly to a wound site via a pump is well known and modifying Westaby with a liquid medication pump would have been routine within the level of one having ordinary skill in the art. Claims 12, 13, 14, 15, 21 and 22 the dependent claims do not appear to contain any additional features, which in combination with the features of any claim to which they refer, add anything new or novel. More specifically, a pressure sensor, presssure sensor controller, and a display are well known features in the art, and the addition of such to a prior art device would only require routine skill in the art. Claim 39, Westaby et al. fail to teach a bendable wire in the tubing. Absent a critical teaching and a showing of unexpected results derived from the usage of such, the examiner contends that the bendable wire is an obvious design choice.

Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over Westaby et al. in view of Harvey. Claim 4, Westaby et al.fail to teach a vacuum pump connected to the (Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

V. 1. REASONED STATEMENTS:
The report as to Novelty was positive (YES) with respect to claims 2-16, 18-35, 37 and 39-44.
The report as to Novelty was negative (NO) with respect to claims 1, 17, 36 and 38.
The report as to Inventive Step was positive (YES) with respect to claims 2, 5-8,16, 18, 19, 20, 23, 24-35 and 40-44.
The report as to Inventive Step was negative (NO) with respect to claims 1, 3, 4, 9-15, 17, 21, 22, 36-38, 39.
The report as to Industrial Applicability was positive (YES) with respect to claims 1-44.
The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
fluid drainage. However, Harvey teaches it is well known to connect a vacuum pump to a fluid drainage line of a wound dressing in order to evacuate fluid from the wound. It would have been obvious to one having ordinary skill in the art to modify Westaby with the addition of a vacuum pump connected to the fluid drainage in order to evacuate fluid from the wound, as suggested by Harvey.

Claims 9-11 are an inventive step under PCT Article 33(3) as being obvious over Westaby et al. in view of Viesturs. Claim 9, Westaby et al.fail to teach an oxygen supply connected to the fluid supply. However, Viesturs teaches it is conventional in the art to connect an oxygen supply to the fluid supply of a wound dressing because of the healing effects associated with providing oxygen to body sores and wounds. It would have been obvious to one having ordinary skill in the art to modify the dressing of Westaby with the addition of an oxygen supply connected to the fluid supply of a dressing because of the healing effects associated with providing oxygen to body sores and wounds. Claims 10 and 11, the addition of other healing fluids such as air, as well as various valving configurations for selecting one or more fluids to be supplied to the wound is also considered an obvious design choice to one having ordinary skill in the art.

Claims 2, 5-8, 16, 18, 19, 20, 23, 24-35, and 40-44 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a wound treatment apparatus comprising the limitations claimed by the instant invention.

---------- NEW CITATIONS ----------
DE 28 09 828 A1 (WESTABY et al.) 21 September 1978, see Fig. 1.

US 4,969,881 A (VIESTURS) 13 November 1990, see the entire document.

US 3,568,675 A (HARVEY) 09 March 1971, see the entire document.

Express Mail No.: EL504450627US

PATENT COOPERATION TREATY

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

TIMOTHY E. NIEDNAGEL
BARNES & THORNBURG
11 SOUTH MERIDIAN STREET
INDIANAPOLIS IN 46204

PCT

NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 59.3(e) and 61.1(b), first sentence and Administrative Instructions, Section 601(a))

Date of mailing *(day/month/year)*	22 MAY 2000
Applicant's or agent's file reference: 7175-64836	**IMPORTANT NOTIFICATION**
International application No.: PCT/US99/17877	International filing date *(day/month/year)*: 06 AUG 99
Priority date *(day/month/year)*: 07 AUG 98	
Applicant: HENLEY, ALAN WAYNE	

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

28 January 2000

2. That date of receipt is:

☑ the actual date of receipt of the demand by this Authority (Rule 61.1(b)).

☐ the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).

☐ the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. ☐ **ATTENTION**: That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide*, Volume II.

☐ *(If applicable)* This notification confirms the information given by telephone, facsimile transmission or in person on: _____

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/US Assistant Commissioner for Patents Box PCT Washington, D.C. 20231 Attn: IPEA/US Facsimile No.	Authorized officer Telephone No. 703-308-3165

Form PCT/IPEA/402 (July 1998)

PCT

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s) :
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

MOSES, Leigh Marie
506 Pointe of Oaks Road
Summerville, SC 29485
US

hereby appoint(s) the following person as: [XX] agent [ ] common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

NIEDNAGEL, Timothy E.; COFFEY, William R.; CONARD, Richard D.; LAMMERT, Steven R.; REZEK, Richard A.; HARRISON, Nancy, J.; CARTER, R. Trevor; KULKARNI, Dilip A.; QUICK, David B.; POWLICK, Jill T.; HEDGES, Norman J.; PALAN, Perry; NEWMAN, Mark M.; GILLENWATER, Bobby B.; HUNT, Paul B.; GZYBOWSKI, Michael S.; GALLAGHER, Gerald T.; NULL, Robert D.; MARTIN, Alice O.; COOPER, Gregory S.; All Appointed Agents of the Address:
BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

to represent the undersigned before

[XX] all the competent International Authorities
[ ] the International Searching Authority only
[ ] the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

US as receiving Office

and to make or receive payments on behalf of the undersigned.

Signature(s) *(where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power).*

Leigh Marie Moses

Leigh Marie MOSES

Date: 30/9/99
9/30/99
Day/ Month/ Year

PCT

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s) :
(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)

SANDERSON, Ronald Leslie
P.O. Box 70543
Charleston, SC 29514
US

hereby appoint(s) the following person as: [XX] agent [ ] common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

NIEDNAGEL, Timothy E.; COFFEY, William R.; CONARD, Richard D.; LAMMERT, Steven R.; REZEK, Richard A.; HARRISON, Nancy, J.; CARTER, R. Trevor; KULKARNI, Dilip A.; QUICK, David B.; POWLICK, Jill T.; HEDGES, Norman J.; PALAN, Perry; NEWMAN, Mark M.; GILLENWATER, Bobby B.; HUNT, Paul B.; GZYBOWSKI, Michael S.; GALLAGHER, Gerald T.; NULL, Robert D.; MARTIN, Alice O.; COOPER, Gregory S.; All Appointed Agents of the Address:
BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

to represent the undersigned before

[XX] all the competent International Authorities
[ ] the International Searching Authority only
[ ] the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

US as receiving Office

and to make or receive payments on behalf of the undersigned.

Signature(s) *(where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power).*

Ronald Leslie Sanderson
Ronald Leslie SANDERSON

Date: 20 09 99
Day/ Month/ Year

PCT

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s):
(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)

HOWARD, John
415 Howle Avenue
Charleston, SC 29412
US

hereby appoint(s) the following person as: [XX] agent [ ] common representative

Name and address
(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)

NIEDNAGEL, Timothy E.; COFFEY, William R.; CONARD, Richard D.; LAMMERT, Steven R.; REZEK, Richard A.; HARRISON, Nancy, J.; CARTER, R. Trevor; KULKARNI, Dilip A.; QUICK, David B.; POWLICK, Jill T.; HEDGES, Norman J.; PALAN, Perry; NEWMAN, Mark M.; GILLENWATER, Bobby B.; HUNT, Paul B.; GZYBOWSKI, Michael S.; GALLAGHER, Gerald T.; NULL, Robert D.; MARTIN, Alice O.; COOPER, Gregory S.; All Appointed Agents of the Address:
BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

to represent the undersigned before

[XX] all the competent International Authorities
[ ] the International Searching Authority only
[ ] the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

US

and to make or receive payments on behalf of the undersigned: as receiving Office

Signature(s) *(where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power):*

John Howard
John HOWARD

(13.09.99)

Date: 9 / 13 / 99
Day / Month / Year

PCT

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s) :
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

PRICE, James H.
1524 Strathmore Lane
Mount Pleasant, SC 29464
US

hereby appoint(s) the following person as: [XX] agent [ ] common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

NIEDNAGEL, Timothy E.; COFFEY, William R.; CONARD, Richard D.; LAMMERT, Steven R.; REZEK, Richard A.; HARRISON, Nancy, J.; CARTER, R. Trevor; KULKARNI, Dilip A.; QUICK, David B.; POWLICK, Jill T.; HEDGES, Norman J.; PALAN, Perry; NEWMAN, Mark M.; GILLENWATER, Bobby B.; HUNT, Paul B.; GZYBOWSKI, Michael S.; GALLAGHER, Gerald T.; NULL, Robert D.; MARTIN, Alice O.; COOPER, Gregory S.; All Appointed Agents of the Address:

BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

to represent the undersigned before

[XX] all the competent International Authorities
[ ] the International Searching Authority only
[ ] the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

US as receiving Office

and to make or receive payments on behalf of the undersigned.

Signature(s) *(where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power).*

PRICE, James H.

Date: (13.09.99) 9 - 13 - 99
Day/ Month/ Year

PCT

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s) :
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

BESSETTE, Russell W.
2157 Main Street
Buffalo, NY 14214
US

hereby appoint(s) the following person as: [XX] agent [ ] common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

NIEDNAGEL, Timothy E.; COFFEY, William R.; CONARD, Richard D.; LAMMERT, Steven R.; REZEK, Richard A.; HARRISON, Nancy, J.; CARTER, R. Trevor; KULKARNI, Dilip A.; QUICK, David B.; POWLICK, Jill T.; HEDGES, Norman J.; PALAN, Perry; NEWMAN, Mark M.; GILLENWATER, Bobby B.; HUNT, Paul B.; GZYBOWSKI, Michael S.; GALLAGHER, Gerald T.; NULL, Robert D.; MARTIN, Alice O.; COOPER, Gregory S.; All Appointed Agents of the Address:

BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

to represent the undersigned before

[XX] all the competent International Authorities
[ ] the International Searching Authority only
[ ] the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

US as receiving Office

and to make or receive payments on behalf of the undersigned.

Signature(s) *(where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power)*:

Russell W. BESSETTE

Date: (25.10.99) 25 October 1999
Day/ Month/ Year

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
7175-64836		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 99/ 17877	06/08/1999	07/08/1998
Applicant		
HENLEY, Alan, Wayne et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
T/US 99/17877

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 41 11 122 A (NEHER) 29 April 1993 (1993-04-29)	1-19
A	* THE WHOLE DOCUMENT *	20-42
X	GB 1 549 756 A (EVERETT ET AL.) 8 August 1979 (1979-08-08)	1
A	abstract; claims 1-6; figures 1-3	2-42
A	US 5 735 833 A (OLSON) 7 April 1998 (1998-04-07) abstract; figures 1-5	1-42
A	US 4 224 941 A (STIVALA) 30 September 1980 (1980-09-30) abstract; figures 1,2	1,9,10

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 October 1999	27/10/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Michels, N

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]T/US 99/17877

C.(Continuation) DOCUMENTS CONSI[redacted]ED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 661 093 A (BECK ET AL.) 28 April 1987 (1987-04-28) ---	
A,P	EP 0 880 953 A (FLEISCHMANN) 2 December 1998 (1998-12-02) -----	

1.

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/17877

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 4111122 A	29-04-1993	DE 3935818 A	02-05-1991
GB 1549756 A	08-08-1979	CA 1127488 A	13-07-1982
		DE 2809828 A	21-09-1978
		FR 2382900 A	06-10-1978
		JP 1338799 C	29-09-1986
		JP 53113188 A	03-10-1978
		JP 61001148 B	14-01-1986
US 5735833 A	07-04-1998	NONE	
US 4224941 A	30-09-1980	NONE	
US 4661093 A	28-04-1987	DE 3321151 A	13-12-1984
		AT 36242 T	15-08-1988
		DE 3473229 A	15-09-1988
		EP 0128388 A	19-12-1984
		JP 1709724 C	11-11-1992
		JP 3075184 B	29-11-1991
		JP 60007851 A	16-01-1985
		JP 1838924 C	25-04-1994
		JP 4261670 A	17-09-1992
		JP 5029469 B	30-04-1993
		US 4792328 A	20-12-1988
		US 4936834 A	26-06-1990
EP 0880953 A	02-12-1998	DE 19722075 C	01-10-1998
		DE 29715634 U	06-11-1997

(19) BUNDESREPUBLIK DEUTSCHLAND

(12) Offenlegungsschrift

(10) DE 41 11 122 A1

(51) Int. Cl.5:
A 61 N 1/36
A 61 M 3/02

DEUTSCHES PATENTAMT

(21) Aktenzeichen: P 41 11 122.2
(22) Anmeldetag: 27. 3. 91
(43) Offenlegungstag: 29. 4. 93

DE 41 11 122 A1

(71) Anmelder:
Neher, Wolfgang, Dr., 7750 Konstanz, DE

(61) Zusatz zu: P 39 35 818.6

(72) Erfinder:
gleich Anmelder

(54) Wundreinigungs- und Therapiegerät

(57) Wundreinigungs- und Therapiegerät. Verfahren zur Reinigung verschmutzter Wunden in der tägl. Praxis. Die technische Aufgabe besteht darin mittels des Gerätes am Krankenbett und in der täglichen Praxis Dekubitalulcera und Ulcus cruris, also Unterschenkelgeschwür und Wundliegen, lokal zu behandeln.

Die Lösung des Problems erfolgt dadurch, daß durch zwei getrennte Drucksaugpumpen und einer Manschette, die mittels Gummizug am Organ befestigt werden kann, einmal durch die in der Manschette sich befindende Drückdüse und Wasserapplikation die Wunde gereinigt wird, die Absaugdüse, die sich etwa am Boden der Manschette befindet saugt gleichzeitig die Spülflüssigkeit ab. Reinigungs- und Therapiesubstanzen können der Lösung beigegeben werden. Durch die Applikation am Krankenbett, kann das oft schwierige Verbringen der Pat. in das Bad etc. vermieden werden. Ein weiterer Applikationsweg, der von den Pat. gerne in Anspruch genommen wird, ist die Behandlung lokaler Prozesse, vor allem im Extremitätenbereich, z. B. rheumatische Schwellungen u. a. hier werden lösliche Antirheumatika der Flüssigkeit beigegeben, und unter Druck direkt auf das erkrankte Organ gebracht. Die Anwendungsgebiete sind demnach Reinigung von Geschwüren aller Art und die Lokalbehandlung von krankhaften Schwellungen. Ob eine Nierenclearence über die Haut und mit Druckanzügen erfolgen kann, bedarf weiterer eingehender Untersuchungen.

DE 41 11 122 A1

Beschreibung

Bezüglich eines Zusatzpatentes für P 39 35 818.6 möchte ich nachträglich folgende Merkmale geltend machen: das Wundreinigungs-Therapiegerät Aquaderm benötigt zwei Pumpaggregate mit getrenntem Kreislauf. Zeichnung dazu wurde Ihnen bereits früher zugesandt. Die Bedienungsanleitung soll ebenfalls Inhalt des Zusatzpatentes sein. Insbesondere soll auch der Manschettenmechanismus geschützt werden, hier sind die Sprüh- und Düsenköpfe Inhalt des Gesamtsystems, diese können mehrdüsig, eindüsig und andere Merkmale aufweisen, auch die Druckgradienten können variieren, so Impulsdruckgradienten, Feineinstellung und massive Druckerhöhung bis zur Gewebsinfiltration. Auch die Absaugmechanismen sind in der Variabilität zu schützen, so können verschiedene Materialien dazu benutzt werden, auch doppelwandige Manschetten sind möglich. Auch die Absaugdüse ist mehreren Variationsmöglichkeiten ausgesetzt. Hier sind die verschiedenen Möglichkeiten unter Patentschutz zu stellen. Insbesondere ist die Gesamtheit des Gerätes, die aus vielen Einzelkomponenten besteht, den Patentregularien zu unterwerfen. Weiter wird ein Druckmanometer installiert werden, Barbereich etwa von 0—3 bar oder auch mehr. Auch ein Temperaturfühler zur Messung der Flüssigkeit ist möglich, ebenso soll eine Kurzzeituhr eingebaut werden, um die Länge der Applikation zu steuern. Auch diese Materialinhalte sind im gesamten Funktionsbild der Geräteeinheit dem Patentschutz zu unterstellen. Bisher sind keine Steuerungsmechanismen der Computerklasse vorgesehen, jedoch sind diese zu einem späteren Zeitpunkt notwendig, so wären auch diese, so sie der Gerätefunktion dienlich sind, zu patentieren.

Die ringförmige, doppelwandige Absaug- und Reinigungsmanschette hätte den Vorteil, daß die Spannbänder wegfallen würden und die Manschette selbständig durch Unterdruck auf der Hautoberfläche haften würde, eine Zeichnung ist zur Demonstration beigegeben. Hierzu wäre in das Gerät noch eine zusätzliche Unterdruckpumpe einzubauen, die auf Luftbasis beruhen würde. Hier ergeben sich vielfältige Variationen, die ebenfalls patentrechtlich geschützt sein sollen.

Was die zu entwickelnden Manschettenköpfe anlangt, so sind diese noch nicht parat, sollen jedoch alsbald produziert werden. Hier sind für die einzelnen Extremitäten verschiedene Paßformen zu entwickeln, wobei das generelle Prinzip der Spülung und Absaugung im Hautbereich beibehalten wird. Auch rektale und vaginale Drucksaugköpfe sind zu entwickeln und patentmäßig zu schützen. Durch durchsichtig gestaltete Manschettenköpfe und entsprechende Druckstrahlerhöhung kann auch eine Art Gewebeschneidung erfolgen, wobei hier jedoch noch stärkere Druckaggregate notwendig sind, die entwickelt werden sollen. Hier kann dann unter Aufsicht bzw. Durchsicht durch die Manschette, es ist auch ein glasfensterartiger Einsatz denkbar, eine lokale Entfernung nekrotischer Wundbestandteile (sogenannte Wundausschneidung) vorgenommen werden. Insgesamt wäre wichtig, daß das geschlossene Zirkulationssystem mit dem Aufsatz der Manschette und der Druck- bzw. Absaugdüse und auch die beschriebenen anderen Gerätschaften dem Patentschutz unterworfen werden.

Bedienungsanleitung Aquaderm

Index

1.1.1. Aufstellung

Stellen sie das Gerät auf die dafür vorgesehene Gummistolle senkrecht oder waagrecht.

1.1.2. Anschluß

a) Verbinden sie das Gerät mit Strom 220 V/50 Hz.
b) Schließen sie die dicken Schläuche seitlich am Zufluß und Abfluß an und stecken sie die Enden in die dafür vorgesehenen Behälter.
c) Verbinden sie die Manschette und das Gerät mit dem dünnen Schlauch sowie Adapterschläuche und achten sie hierbei, daß der linke Anschluß der Zuführungsschlauch ist, der an die obere Seite der Manschette führt.

1.1.3. Einschalten

Sie können jederzeit das Gerät einschalten. Wichtig ist dabei sich vorher zu versichern, daß der Einstellhahn zugedreht (Rechtsanschlag) ist.

Beim Anwenden drehen sie langsam auf bis der gewünschte Druck erreicht ist. Die beste Wirkung erzielen sie bereits nach einer halben Drehung.

1.1.4. Applikation der Manschette

Beim Anbringen der Manschette muß darauf geachtet werden, daß die Manschette nicht in sich zusammengedrückt wird und die Absaugung am untersten Punkt angebracht ist.

Der Patient kann unter Umständen selber die Manschette halten mit einem leichten Druck. Sie können sonst auch die mitgelieferten Spannbänder benutzen.

1.1.5. Wissenschaftliche Anwendung

Dauer und Handhabung von Wundbehandlungen entnehmen sie bitte der wissenschaftlichen Begleitanleitung.

2.1.6. Reinigung und Desinfektion der Manschette

Nach der Anwendung ziehen sie die Manschettenschläuche an der Manschettenseite ab und legen sie in eine Desinfektionslösung.

Stecken sie jetzt die zweite Manschette auf die Schläuche, behandeln sie weiter.

2.1.7. Reinigung und Desinfektion des Gerätes

Wenn immer mit zwei Behältern gearbeitet wird, braucht eine Desinfektion des Systems nicht durchgeführt zu werden. Es ist trotzdem ratsam das System

einmal wöchentlich zu spülen. Nenmen sie hierzu eine Essiglösung oder Desinfektionslösung. Verbinden sie hierzu die Manschettenschläuche und benutzen den Reinigungsbehälter im Dauerumlauf.

2.1.8. Nach der Benutzung

Nach der Benutzung sollten sie, um die Restflüssigkeit zu entfernen, den Ansaugschlauch aus dem Behälter ziehen und warten, bis nur wenig Flüssigkeitsreste aus dem Schlauchsystem fließen.

3.1.9. Probleme

a) Wenn die Schläuche nicht mehr richtig dicht sind, schneiden sie ein Stück ab und ziehen sie neu auf.
b) Wenn die Absaugung an der Manschette nicht funktioniert, reinigen sie die Absaugdüse. Um eine weitere Wasserflut zu verhindern, testen sie erst ohne Manschette durch Verbinden der Manschettenschläuche.
c) Durch 2 Wasserabscheider im Boden des Gerätes oder in der Bodenplatte kann die Flüssigkeit aus dem Gerät heraus, falls eine Undichtigkeit auftritt. Benachrichtigen sie in diesem Falle ihre Lieferanten oder schrauben sie das Gerät an den 8 Dekkelschrauben auf und suchen sie das Leck. Eventuell können sie kleine Undichtigkeiten selber beheben.

4.1.1. Wichtige Hinweise

Bei Applikationen mit Medikamenten im Dauerumlauf sollte das Gerät mit einer Desinfektionslösung gespült werden, um höchste Hygiene zu erreichen.

Das Gerät sollte ein- bis zweimal jährlich auf eventuelle Undichtigkeit durch Sichtkontrollen geprüft werden.

Achten sie darauf den Regulierer immer auf Rechtsanschlag zu drehen, bevor das Gerät eingeschaltet wird.

Nach einer Behandlung muß, bevor die Manschette abgenommen wird, der Regulierer zugedreht werden, damit der Restwasseranteil in der Manschette abgesaugt werden kann.

5.1.1. Checkliste für die tägliche Wundreinigung

1. Stromverbindung herstellen.
2. Zulauf/Ablauf mit dickem Siliconschlauch verbinden.
3. Manschette und dünne Schläuche verbinden und über Adapter mit dem Gerät verbinden. Schlauch im Behälter auf richtigen Sitz prüfen.
4. Regulierer auf Rechtsanschlag prüfen.
5. Gerät einschalten.
6. Manschette applizieren.
7. Regulierer auf ca. 1/2 Umdrehung aufdrehen.
8. Nach Behandlung Manschette wechseln.
9. Benutzte Manschette desinfizieren.
10. Flüssigkeiten entfernen.
11. Gerät spülen und entleeren oder
12. Gerät mit Desinfektionslösung kurz spülen und entleeren.

Technische Daten

a) Stromversorgung
Stromaufnahme 80 Watt

Spannung versorgen 220 V / 50 Hz
Pumpenspannung 12 V / 3 A

b) Pumpenleistung
1 Liter pro Minute
Druckregulierung über Ventilrelais

c) Prinzip
1 Pumpenaggregat für Ansaugung
1 Pumpenaggregat für Absaugung
Geregelt mit Regulierer

Medizinische Indikationsbeschreibung des Wundreinigungsgerätes AQUADERM

Mittels der aufsetzbaren Manschette und der Reinigungsdüse kann bei ulcerösen Prozessen im Hautbereich, die meist mit pathogenen Keimen (Staphylokokken, Streptokokken) superinfiziert sind, eine problemlose Reinigung des Wundgrundes erfolgen. Im klinischen Bereich gilt die Wundreinigung bei Ulcus cruris (Dekubitalgeschwüre, Dekubitalsepsis u. a.) als eine Voraussetzung zum Wundheilungsprozeß.

Bei der Applikation der Reinigungsmanschette sind zuvor die Wundgranulationen zu entfernen, dies geschieht am besten mittels einer Pinzette, danach kann die desinfizierende und reinigende Wasserlösung appliziert werden. Der Vorgang kann unbedenklich bis zum Abheilen des Geschwürs mehrmals wöchentlich erfolgen.

Der Wundrand ist mit einer wundpflegenden Salbe zu bestreichen, dann sterile Abdeckung.

Durch Ödeme, Varizen u. a. ist im Unterschenkelbereich stauungsbedingt eine schlechtere Sauerstoffversorgung vorhanden und der dadurch geschädigte Hautbereich vermehrt für infektiöse Prozesse und Ulcerationen anfällig. Deshalb ist in diesem Bereich eine peinliche Hygiene erforderlich, insbesondere sind Kratzeffekte und kleine Rhagaden zu vermeiden, der Spüllösung können auch Penizilline in löslicher Form u. a. Medikamente zugesetzt werden. Ein weiteres Indikationsgebiet zur Aquatherapie sind rheumatisch bedingte Schwellungen im Bereich großer Gelenke, hier kann allein durch gezielte Anwendung von wärmendem Wasser eine Umstimmung erfolgen, durch Zugabe von Kortikosteroiden, Salizylaten, Antirheumatika (in Form von Lösungen oder auch löslichen Tabletten) ist eine Potenzierung des Erfolges möglich.

Gesicherte Erkenntnisse liegen jedoch hierzu noch nicht vor. Weiteres Indikationsgebiet sind degenerative Prozesse sowie punktförmige Knochenhautreizungen, wie Periostitis und Epicondylitis etc. Hier kann durch Druckstrahlerhöhung der Prozeß therapeutisch günstig beeinflußt werden.

Die Kombination aus dem Aquaderm und einem Reizstromgerät, ähnlich wie bei einem Stangerbad, nur in Kleinformat, soll patentiert werden. Zu der bekannten Aquatherapie soll in geeigneter Form eine Elektrode in der Manschette angebracht werden, die auch bipolar, also in Mehrfachform, Reizströme in Wasser vermittelt.

Stand der Technik mit Fundstellen

1. Es ist bekannt, daß venöse Beinulcera sehr häufig sind, es wird geschätzt, daß ein Prozent der Bevölkerung von diesem Leiden befallen ist (Ärztliche Praxis Nr. 85 vom 23. 10. 90). Das Leiden ist oft

therapieresistent. Ähnliches gilt für das Dekubitalulcus, also das Wundliegen, die Pflege ist sehr aufwendig, die Reinigung des Wundgrundes erfolgt mittels Salbenapplikation und mit Ringerlösung getränkten Umschlägen (Ärztliche Praxis Nr. 65 vom 14. August 90). Es ist ferner bekannt, daß vom Gesetzgeber sehr strenge Anforderungen an die Behandlung des Wundliegens gestellt werden, da dieses Leiden oft zum Tode führen kann.

2. Problem: Der im Patentanspruch 1 angegebenen Erfindung liegt das Problem zugrunde, die mit Bakterien verunreinigten Wunden, die sich in Form von schmierigen Belägen darstellen, zu beseitigen, um so einen optimalen Heilungsverlauf zu erzielen.

3. Die Lösung dieses Problems wird durch die im Patentanspruch 1 aufgeführten Merkmale erzielt.

4. Die mit der Erfindung erzielten Vorteile bestehen insbesondere darin, daß statt einer Vielzahl von Salbenauflagen und sonstigen Verbänden, die das Leiden sogar verschlimmern können, durch einige wenige Applikationen des Gerätes der schmierige Untergrund gesäubert wird, und dadurch die Heilung des Geschwürs erfolgt. Bettlägrige Patienten müssen nicht mehr aufwendig ins Bad zur Reinigung der Wunden verbracht werden. Bei Erprobung in der Praxis sind derartige Vorteile erzielt worden.

5. Eine vorteilhafte Ausgestaltung der Erfindung ist im Patentanspruch 2 angegeben, wobei die Größe der Gummiglocken variabel gestaltet werden kann. In einfacher Weise ist es durch dieses System möglich, verschiedene Substanzen zur Therapie zuzugeben, indem diese der Spülflüssigkeit zugemischt werden. Durch diese Anordnung können auch entzündliche Veränderungen, wie z. B. bei Gelenkrheumatismus, einer kausalen Behandlung zugänglich gemacht werden, indem unter Druck Medikamente intrakutan verabreicht werden.

Patentansprüche

1. Wundreinigungsgerät und Therapiegerät zur Applikation in der Praxis und Klinik, wobei durch eine über der Wunde aufsetzbare Gummimanschette oder auch Gummiglocke genannt, eine geschlossene feuchte Kammer entsteht. Durch eine Spüldüse, die im oberen Bereich der Gummiglocke befestigt ist, erfolgt die Reinigung des Geschwürsgrundes, eine weitere Absaugdüse im unteren Bereich der Glocke sorgt für den Abtransport der Spülflüssigkeit. Zwei unabhängig voneinander arbeitende Pumpen besorgen den kontinuierlichen Kreislauf. Aus einem Behälter wird die Spülflüssigkeit angesaugt und in einen weiteren oder auch denselben Behälter wird die abgesaugte Flüssigkeit, die nun verunreinigt ist, wieder eingegeben.

2. Die Gummimanschette nach Anspruch 1 kann verschiedene Paßformen aufweisen. Die Fixierung der Gummimanschette erfolgt mittels eines Gummizugbandes, das perforierte Öffnungen aufweist.

Hierzu 2 Seite(n) Zeichnungen

Nummer: DE 41 11 122 A1
Int. Cl.: A 61 N 1/36
Offenlegungstag: 29. April 1993

SPEZIFIKATION HP 60 L

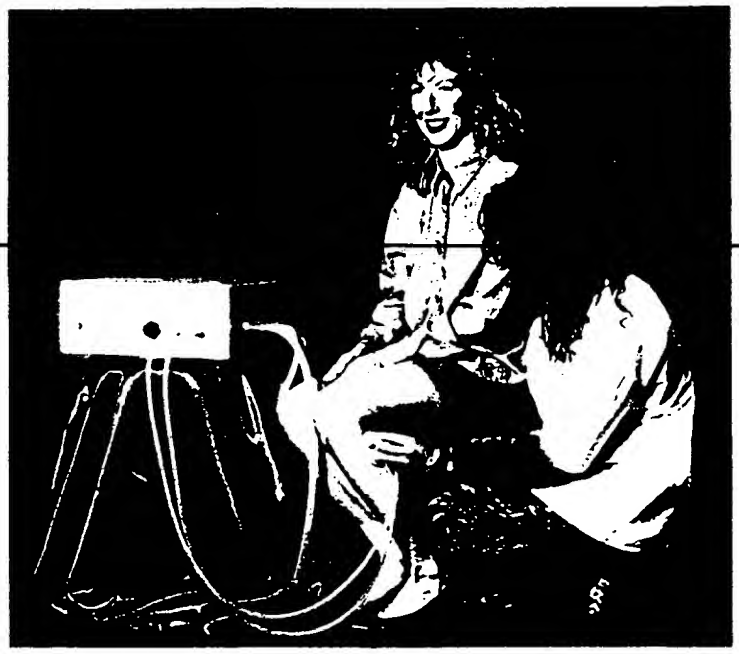


Fig 1

Bisher erfolgreich getestete Indikationen

Ulcus cruris
Dekubitalgeschwüre

schlecht heilende Wunden mit
lymphangitischen Erscheinungen.
Aquatherapie bei Myalgien, degenerativen Prozessen,
rheumatischen Schwellungen

Technische Daten

Stromaufnahme	80 Watt
Netzanschluß	220V/ 5
Pumpenspannung	12V/ 3
Sicherheit	VDE
Maße	40 x 35 x 16
Gewicht	ca. 10 kg

Therapeutische Anwendungsmöglichkeiten

Altenpflege
Chirurgie
Klinischer Pflegebereich
Naturheilkunde
Orthopädie

Standardausstattung

Gerät (ohne Wagen)
4 Schläuche

Manschetten

Applikationen

Problemlose Anwendung am Krankenbett
In der ambulanten Sprechstunde

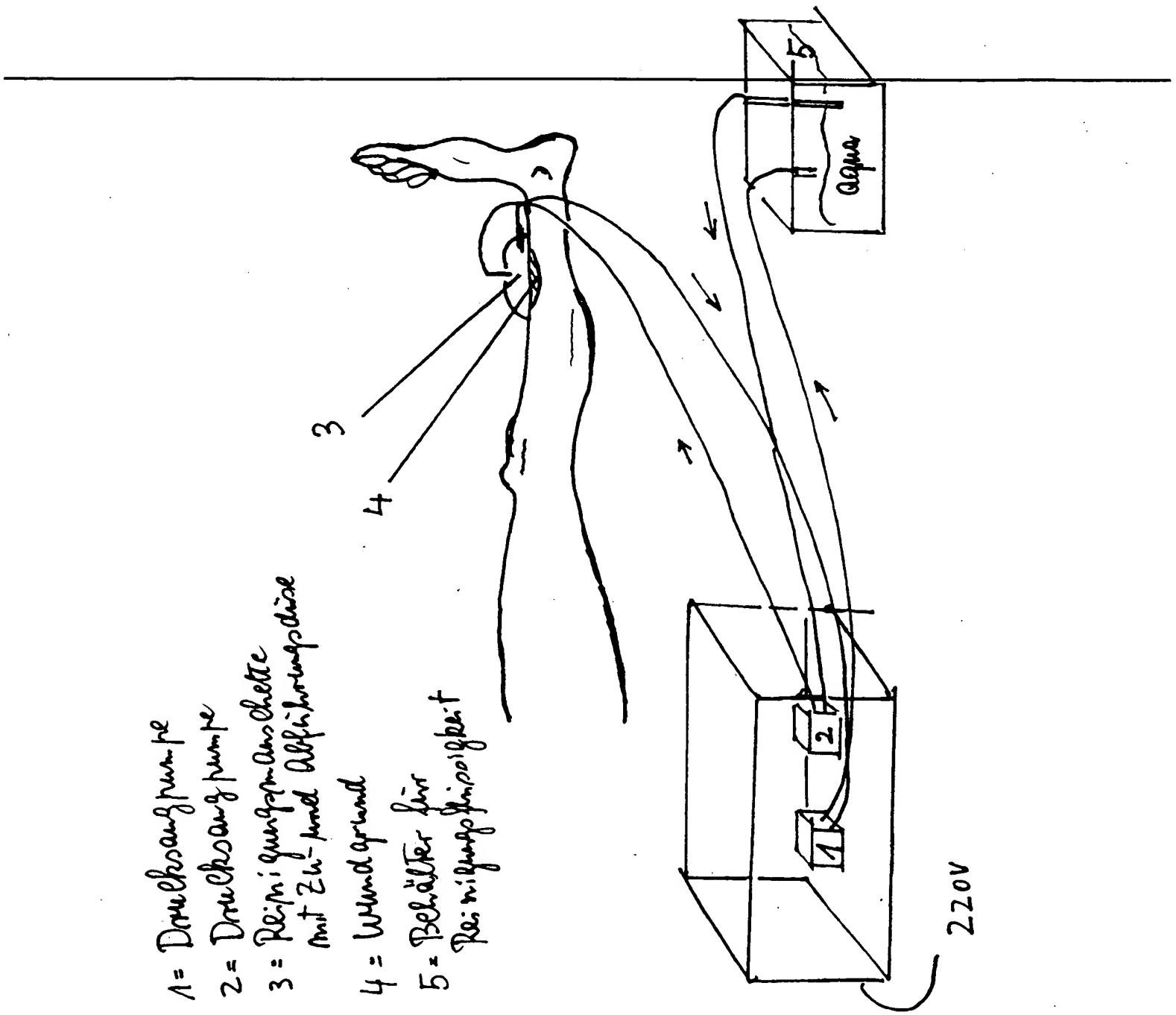
Wahlzubehör

Geratewagen
Schlauche
Mannschetten

Durch geschlossenen Wasserkreislauf ist ein Anschluß an das Wassernetz nicht erforderlich.

Nummer: DE 41 11 122 A1
Int. Cl.5: A 61 N 1/36
Offenlegungstag: 29. April 1993

Fig 2



(19) Europäisch tentamt
European Patent Office
Office européen des brevets

(11) EP 0 880 953 A2

(12) EUROPÄISCHE PATENTANMELDUNG

(43) Veröffentlichungstag:
02.12.1998 Patentblatt 1998/49

(51) Int. Cl.[6]: **A61F 13/00**

(21) Anmeldenummer: **98108773.7**

(22) Anmeldetag: **14.05.1998**

(84) Benannte Vertragsstaaten:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Benannte Erstreckungsstaaten:
AL LT LV MK RO SI

(30) Priorität: **27.05.1997 DE 19722075**
30.08.1997 DE 29715634 U

(71) Anmelder:
Fleischmann, Wilhelm, Dr. med.
89182 Bernstadt (DE)

(72) Erfinder:
Fleischmann, Wilhelm, Dr. med.
89182 Bernstadt (DE)

(74) Vertreter:
Patentanwälte
Westphal, Buchner, Mussgnug
Neunert, Göhring
Waldstrasse 33
78048 Villingen-Schwenningen (DE)

(54) Vorrichtung zur Applikation von Wirkstoffen an einer Wundoberfläche

(57) Zur Applikation von Wirkstoffen an einer Wundoberfläche wird auf die Wunde (10) eine poröse Einlage (12) aufgebracht, die von einer Folie (14) dicht abgedeckt wird. Ein flüssiger Wirkstoff wird über eine Zuleitung (22) in die Einlage (12) eingeleitet und wird über eine Ableitung (26) wieder aus der Einlage (12) abgesaugt. Absperrorgane (32, 34) steuern das Einleiten des Wirkstoffes und das Absaugen des Wirkstoffes in der Weise, daß der Wirkstoff nach dem Einleiten für eine gewisse Einwirkungsdauer in der Einlage (12) verbleibt, bevor er abgesaugt wird. Nach dem Absaugen wird der Unterdruck in der Einlage (12) über eine gewisse Zeitdauer aufrechterhalten, bevor erneut der Wirkstoff eingeleitet wird. Das Öffnen der Absperrorgane (32, 34) erfolgt zeitlich gesteuert langsam.

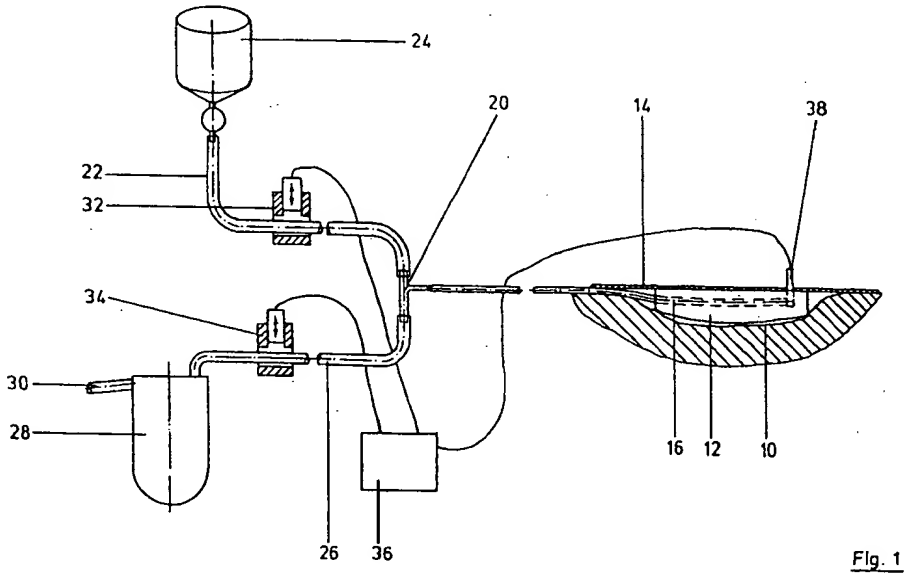


Fig. 1

EP 0 880 953 A2

Beschreibung

Die Erfindung betrifft eine Vorrichtung zur Applikation von Wirkstoffen an einer Wundoberfläche gemäß dem Oberbegriff des Anspruchs 1.

Zur medikamentösen lokalen Behandlung von Wunden werden bislang Salben, Lösungen oder feste Medikamententräger, wie resorbierbare Kollagene, antibiotikumgetränkter Knochenzement oder imprägnierte Wundauflagen, verwendet. Insbesondere bei tieferen Wunden besteht die Schwierigkeit, daß Salben nicht anwendbar sind, Lösungen von Verbandsstoffen aufgesaugt werden und häufig nicht in genügendem Maße mit der inneren Wundoberfläche in Kontakt kommen, um ihre therapeutische Wirkung zu entfalten. Bei der Implantation von körperfremden Arzneimittelträgern, wie Knochenzement oder resorbierbaren Materialien, entsteht ein Wirkungsverlust durch Verdünnung mit Wundsekret. Außerdem stehen nur wenige Arzneimittel zur Verfügung, die eine lokale Langzeit-Depotwirkung entfalten. Im Gewebe kann unter Umständen eine schädliche Fremdkörperreaktion entstehen. Abbaubare Medikamententräger können bei ihrem Zerfall zu unerwünschten Nebenwirkungen führen.

Aus der DE 40 12 232 A1 ist ein Redon- bzw. Instillationsverband für die Behandlung oberflächlicher und tiefer Problemwunden, insbesondere mit Infektionen, bekannt, bei welchem die Wunde durch eine dünne semipermeable Folie abgedeckt wird. Eine Zuleitung und eine Ableitung führen unter die Folie in den Wundbereich. Über die Zuleitung können mittels einer Spritze Wirkstoffe an die Wundoberfläche unter der Folie appliziert werden. Nach der gewünschten Einwirkzeit können die Wirkstoffe gegebenenfalls zusammen mit dem Wundsekret über die Ableitung mittels einer Unterdruckquelle abgesaugt werden. Die Zuleitung weist ein selbsttätig schließendes Sicherheitsventil auf, welches durch die eingeführte Spritze zum Zuführen der flüssigen Wirkstoffe geöffnet wird. Ebenso ist an der Ableitung ein Absperrorgan vorgesehen, welches die Ableitung während der Einwirkungsdauer des Wirkstoffes verschließt.

Bei diesem bekannten Instillationsverband wird der Wirkstoff unmittelbar auf die Wundoberfläche gebracht und von der Wundoberfläche abgesaugt. Der Wirkstoff kann daher nur ungenau dosiert einwirken und insbesondere bei größeren Wundoberflächen ist eine gleichmäßige Einwirkung auf die gesamte Oberfläche kaum erreichbar. Eine Langzeit-Depotwirkung kann nicht realisiert werden.

Aus der US 4,382,441 ist es bekannt, zur Behandlung von Wundoberflächen eine Einlage aus einem porösen Material auf die Wundoberfläche aufzulegen und diese abdichtend zu überdekken. Der zu applizierende Wirkstoff wird kontinuierlich durch die Einlage geleitet, wozu eine Zuleitung und eine Ableitung in die Einlage führen. Die Kapillarwirkung der porösen Einlage begünstigt die Verteilung des zugeführten Wirkstoffes über die gesamte mit der Wundoberfläche in Berührung stehende Oberfläche der Einlage.

Die poröse Einlage ist weitgehend formstabil und auch die abdichtende Auflage ist vorzugsweise formstabil. Der flüssige Wirkstoff wird in kontinuierlicher Strömung durch die Einlage geleitet, wobei sich eine Strömungsverteilung ausbildet, bei welcher der flüssige Wirkstoff im wesentlichen in dem Bereich zwischen Zuleitung und Ableitung fließt, während die Randbereiche der Einlage kaum durchströmt werden. In diesen Randbereichen wird der Wirkstoff daher kaum ausgetauscht und auch in den Randbereichen aufgenommenes Wundsekret wird nur ungenügend abgeführt. Die relativ formstabile Einlage liegt zudem nicht in allen Bereichen gleichmäßig an der Wundoberfläche an, so daß auch hierdurch eine gleichmäßige Applikation des Wirkstoffes und eine gleichmäßige Abführung des Wundsekrets beeinträchtigt wird. Eine Depotwirkung ist nicht beabsichtigt.

Der Erfindung liegt die Aufgabe zugrunde, eine Vorrichtung zur Applikation von Wirkstoffen an einer Wundoberfläche zur Verfügung zu stellen, welche eine hohe Wirksamkeit des applizierten Wirkstoffes auf der gesamten Wundoberfläche gewährleistet, eine optimale Dosierung des Wirkstoffes ermöglicht und den Wundheilungsprozeß begünstigt.

Diese Aufgabe wird erfindungsgemäß gelöst durch eine Vorrichtung gemäß dem Anspruch 1.

Vorteilhafte Ausführungsformen und Weiterbildungen der Erfindung sind in den rückbezogenen Unteransprüchen angegeben.

Der Grundgedanke der Erfindung besteht darin, eine Einlage aus einem elastisch kompressiblen porösen Material auf die Wundoberfläche aufzulegen und die Wundoberfläche und die Einlage durch eine abdichtende Folie abzudecken, die die Wunde und die Einlage gegen die Atmosphäre abschließt. Die Zuleitung und die Ableitung sind jeweils mit steuerbaren Absperrorganen ausgestattet, die zeitlich so gesteuert werden, daß das Einleiten der Wirkstoffe und das Absaugen der Wirkstoffe und gegebenenfalls des Wundsekrets zeitlich voneinander getrennt sind. Zwischen dem Zeitintervall, in welchem das Absperrorgan der Zuleitung geöffnet ist und der Wirkstoff zugeführt wird, und dem Zeitpunkt, in welchem das Absperrorgan der Ableitung geöffnet wird, um den Wirkstoff und das Wundsekret abzusaugen, wird ein Einwirkungszeitintervall geschaltet, in welchem beide Absperrorgane geschlossen sind und der Wirkstoff statisch auf die Wundoberfläche einwirkt. Nach dem Absaugen des Wirkstoffes und des Wundsekrets wird außerdem ein Zeitintervall geschaltet, in welchem das Absperrorgan der Zuleitung geschlossen bleibt und ein Unterdruck im Bereich der Wunde aufrechterhalten wird. Hierzu kann das Absperrorgan der Ableitung geöffnet bleiben, um über die Unterdruckquelle einen konstanten Unterdruck im Wundbereich aufrechtzuerhalten und das Wundsekret abzusaugen. Das Absperrorgan der Ableitung kann

auch geschlossen werden, so daß der anfangs erzeugte Unterdruck aufrechterhalten bleibt. Es ist auch möglich, in dieser Phase das Absperrorgan der Ableitung zeitweise gesteuert zu öffnen, um den Unterdruck wieder herzustellen, falls dieser unter einen vorgegebenen Wert nachläßt.

Das Einwirkungs-Zeitintervall, in welchem die Einlage mit dem Wirkstoff getränkt ist und der Wirkstoff mit Depotwirkung auf die Wundoberfläche appliziert wird, wird entsprechend der Art des Wirkstoffes, seiner Dosierung und der durch den Zustand der Wundoberfläche gegebenen Indikation gewählt. In den Unterdruckzeitintervallen, in welchen kein Wirkstoff appliziert wird und nur das Wundsekret abgesaugt wird, können die körpereigenen immunologischen Reparatur- und Abwehrprozesse des Gewebes ungestört ablaufen, so daß die Wundheilung optimiert wird. Es wechseln somit Einwirkungsphasen und Heilungsphasen zeitlich nacheinander ab. In den Einwirkungsphasen wird mittels Wirkstoffen, wie z.B. Antibiotika oder Antiseptika, aktiv in das Wundsystem eingegriffen, um Infektionen und dgl. zu bekämpfen. Da solche Wirkstoffe neben der gewünschten Hauptwirkung in der Regel auch unerwünschte Nebenwirkungen haben, werden im Anschluß an die Einwirkungsphase die Wirkstoffe abgesaugt und mit diesen das Wundsekret, welches die während der Einwirkungsphase entstehenden Zerfallsprodukte mit ihren unter Umständen toxischen Wirkungen enthält. In dem anschließenden Unterdruckzeitintervall kann der körpereigene immunologische Heilungsprozeß optimal ablaufen, ohne durch die unerwünschten Nebenwirkungen der Wirkstoffe und die bei der Bekämpfung der Wundinfektion entstehenden Zerfallsprodukte beeinträchtigt zu werden.

Vorzugsweise werden die Absperrorgane der Zuleitung und Ableitung zeitlich so gesteuert, daß die Einleitung der Wirkstoffe nur langsam und mit geringem Volumenstrom beginnt. Dadurch wird verhindert, daß durch ein zu plötzliches und schnelles Einleiten des Wirkstoffes Wundschmerzen verursacht oder verstärkt werden. Ebenso erfolgt das Öffnen des Absperrorgans der Ableitung zeitlich gesteuert in der Weise, daß der Unterdruck nur langsam zunmimmt. Ein zu schnell, schlagartig erzeugter Unterdruck führt ebenfalls zu erheblichen Wundschmerzen.

Die auf die Wundoberfläche aufgebrachte Einlage besteht aus einem elastisch kompressiblen porösen Material, vorzugsweise einem PVA-Schwamm (Polyvinylalkohol-Schwamm), wobei eine flexible Folie zur Abdeckung verwendet wird. Wird in dem durch die Folie abgedeckten Wundbereich ein Unterdruck erzeugt, so legt sich die Folie dicht auf die Wunde auf und drückt die Einlage zusammen. Dadurch legt sich die Einlage über ihre gesamte Fläche gleichmäßig dicht an die Wundoberfläche an. Dies begünstigt das Absaugen des Wundsekrets während des Unterdruckzeitintervalls. Wird zum Einleiten des Wirkstoffs die Zuleitung geöffnet, so saugt die poröse Einlage den Wirkstoff auf, wobei sie sich aufgrund ihrer elastischen Rückstellkraft ausdehnt. Dadurch wird bewirkt, daß die Einlage sich wie ein Schwamm gleichmäßig mit dem Wirkstoff vollsaugt. Der Wirkstoff ist über die gesamte Fläche der Einlage gleichmäßig verteilt und wirkt auf die gesamte Wundoberfläche in gleicher Weise ein. Begünstigt wird dies dadurch, daß sich die Einlage in der Unterdruckphase dicht an die Wundoberfläche anlegt. Die gleichmäßige Verteilung des Wirkstoffes über die gesamte Oberfläche wird während der Einwirkungszeit nicht beeinträchtigt, da nach dem Ende des Einleitens während des Einwirkungszeitintervalls ein statischer Zustand herrscht, in dem Zuleitung und Ableitung verschlossen sind.

Da sich die Wundbehandlung über eine längere Zeit, z. B. über einige Tage erstrecken kann, kann es vorkommen, daß insbesondere während einer längeren Unterdruckphase die Poren der Einlage geringfügig verkleben. Solche Verklebungen erhöhen den Widerstand für das Einleiten des Wirkstoffes. Dadurch kann ein Einleiten des Wirkstoffes unter Schwerkraft behindert werden. In solchen Fällen ist es zweckmäßig, zu Beginn des Einleitens des Wirkstoffes die poröse Einlage zunächst freizuspülen. Hierzu wird bei Beginn des Einleitens des Wirkstoffes zunächst ein kleineres Volumen des flüssigen Wirkstoffes unter Druck zugeführt, um die Poren der Einlage zu durchspülen und Verklebungen zu lösen. Das Einleiten unter Druck kann vorzugsweise durch eine Spritze erfolgen, die an die Zuleitung angeschlossen wird. Über den Kolbendruck der Spritze kann zunächst der Wirkstoff mit dosiertem Druck zum Freispülen zugeführt werden, bevor das Einleiten des Wirkstoffes durch Schwerkraft erfolgt. Gegebenenfalls ist es auch möglich, die erforderliche Menge des flüssigen Wirkstoffs während der gesamten Einleitungsphase mittels einer Spritze zuzuführen.

Im folgenden wird die Erfindung anhand von in der Zeichnung dargestellten Ausführungsbeispielen näher erläutert. Es zeigen

Figur 1	die Vorrichtung zur Applikation von Wirkstoffen in einer ersten Ausführung,
Figur 2	eine Abwandlung der Vorrichtung,
Figur 3	ein Zeitdiagramm des Verfahrens, und
Figuren 4 bis 8	verschiedene Ausführungsbeispiele für die Absperrorgane der Vorrichtung.

Zur Behandlung einer großflächigen tiefen Wunde 10 wird in diese eine Einlage 12 eingelegt. Die Einlage 12 besteht aus einem porösen elastisch kompressiblen Material, vorzugsweise aus einem offenporigen PVA-Schaumstoff. Die Einlage 12 wird entsprechend der

Kontur der Wunde 10 zugeschnitten. Die Wunde 10 und die Einlage 12 werden durch eine Folie 14 abgedeckt und dichtend abgeschlossen. Die Folie 14 wird so zugeschnitten, daß sie die Einlage 12 und die Wunde 10 überdeckt und über die Ränder der Wunde hinausragt. Die Folie 14 wird rings um den Wundrand auf der Hautoberfläche dichtend befestigt, z.B. aufgeklebt. Die Folie 14 ist flexibel und besteht aus einem Kunststoffmaterial, welche die Diffusion von Wasserdampf gestattet, jedoch einen luftdichten Abschluß gewährleistet.

In die Einlage 12 wird ein Drainageschlauch 16, ein sogenannter Redon-Schlauch, eingezogen, der in seinem in der Einlage 12 liegenden Endbereich perforiert ist. Der nicht perforierte Bereich des Drainageschlauches 16 wird abgedichtet unter der Folie 14 herausgeführt.

Im Ausführungsbeispiel der Figur 1 ist in das proximale Ende des Drainageschlauchs 16 ein T-förmiges Verzweigungsstück 20 eingesetzt. An den einen Anschluß des Verzweigungsstückes 20 ist ein Schlauch als Zuleitung 22 angesetzt, der zu einem an sich bekannten Infusionsbehälter 24 führt. An den anderen Anschluß des Verzweigungsstückes 20 ist ein Schlauch als Ableitung 26 angeschlossen, der zu einem Auffangbehälter 28 führt, an welchen über eine Anschlußleitung 30 eine Unterdruckquelle anschließbar ist. Ein solcher Auffangbehälter 28 ist ebenfalls an sich bekannt.

Der Zuleitung 22 ist ein Absperrorgan 32 zugeordnet und der Ableitung 26 ist ein Absperrorgan 34 zugeordnet. Die Absperrorgane 32 und 34 sind kontinuierlich zwischen einer Schließstellung und einer Offenstellung verstellbar und werden durch eine Steuerung 36 betätigt.

Im dargestellten Ausführungsbeispiel sind die Absperrorgane 32 und 34 jeweils als Schlauchklemmen ausgebildet, die eine Aufnahme aufweisen, in welche der Schlauch der Zuleitung 22 bzw. der Ableitung 26 eingelegt werden kann. Ein Stempel wird, wie in der Zeichnung durch Pfeile angedeutet ist, von der Steuerung 36 gesteuert elektromagnetisch, pneumatisch, hydraulisch oder in sonstiger bekannter Weise betätigt, um den eingelegten Schlauch gegen ein Widerlager zu drücken und quetschend zu verschließen oder um den Durchtrittsquerschnitt des Schlauches kontinuierlich freizugeben.

In den Wundraum unter der Folie 14 kann gegebenenfalls ein Drucksensor 38 eingesetzt werden, der den unter der Folie 14 herrschenden Druck mißt und der Steuerung 36 meldet.

In dem Infusionsbehälter 24 wird ein flüssiger Wirkstoff bevorratet, der bei geöffnetem Absperrorgan 32 und geschlossenem Absperrorgan 34 über die Zuleitung 22 und den Drainageschlauch 16 in die Einlage 12 und damit an die Wundoberfläche geleitet werden kann. Bei geschlossenem Absperrorgan 32 und geöffnetem Absperrorgan 34 können der Wirkstoff und das in der Wunde 10 erzeugte Wundsekret über die Ableitung 26 in den Auffangbehälter 28 abgesaugt werden.

Figur 2 zeigt eine Abwandlung der Vorrichtung, die sich gegenüber dem Ausführungsbeispiel der Figur 1 darin unterscheidet, daß in die in die Wunde 10 eingelegte Einlage 12 zwei Drainageschläuche 16 und 18 eingezogen sind. Der Drainageschlauch 16 ist mit der Zuleitung 22 verbunden, während der Drainageschlauch 18 mit der Ableitung 26 verbunden ist. Eine Verzweigung entfällt dabei.

In dem Ausführungsbeispiel der Figur 1 bildet der Drainageschlauch 16 ein blindes Schlauchende, in welches einerseits der Wirkstoff eingeleitet und aus welchem andererseits der Wirkstoff abgesaugt wird. Dabei können beim Einleiten des flüssigen Wirkstoffes Gasbläschen in dem Drainageschlauch 16 gefangen werden, die das Einleiten des Wirkstoffes behindern. Diese Schwierigkeiten können bei der Ausführung der Figur 2 nicht auftreten, da eventuell in dem Drainageschlauch 16 gefangene Gasbläschen über den Drainageschlauch 18 abgesaugt werden. Die Ausführung der Figur 1 hat jedoch den Vorteil, daß nur ein Drainageschlauch abgedichtet unter die Folie 14 geführt werden muß.

Anhand der Figur 3 wird das mit der Vorrichtung der Figuren 1 und 2 durchgeführte erfindungsgemäße Verfahren erläutert.

In Figur 3 ist der Druck P in der Wunde 10 unter der Folie 14 als Funktion der Zeit t dargestellt. Die eingezeichnete Abszissenachse entspricht dabei dem Atmosphärendruck.

Zum Zeitpunkt t_1 sind die Absperrorgane 32 und 34 gesteuert durch die Steuerung 36 geschlossen. In der Wunde herrscht ein Unterdruck von etwa 10 bis 80 kPa. Aufgrund dieses Unterdrucks wird die Folie 14 gegen die Wundoberfläche gedrückt, wobei die elastische Einlage 12 komprimiert wird. Zum Zeitpunkt t_1 wird nun gesteuert durch die Steuerung 36 das Absperrorgan 32 geöffnet, so daß der flüssige Wirkstoff aus dem Infusionsbehälter 24 über die Zuleitung 22 und den Drainageschlauch 16 in die Einlage 12 fließen kann. Während des Einleit-Zeitintervalls T_1 saugt sich die Einlage 12 mit flüssigem Wirkstoff voll, wobei sie sich aufgrund ihrer elastischen Rückstellkraft ausdehnt. Zum Zeitpunkt t_2 ist die Einlage 12 mit dem flüssigen Wirkstoff vollgesogen, wobei unter der Folie 14 ein gewisser Überdruck herrscht, der vorzugsweise durch die Höhe des Infusionsbehälters 24 gegenüber der Wunde 10 bestimmt ist. Gegebenenfalls kann auch eine mittels des Drucksensors 38 druckgesteuerte Pumpe in die Zuleitung 22 eingeschaltet werden.

Das Öffnen des Absperrorgans 32 der Zuleitung 22 in dem Einleit-Zeitintervall T_1 erfolgt mittels der Steuerung 36 zeitlich in der Weise gesteuert, daß der durchtretende Volumenstrom des flüssigen Wirkstoffes nur langsam ansteigt, wie dies in Figur 3 durch die ausgezogene Linie dargestellt ist. Ein schlagartiges Öffnen des Absperrorgans 32 würde zu einem sehr schnellen Einfließen des Wirkstoffes führen, wie es in Figur 3 strichpunktiert eingezeichnet ist. Dies könnte zu Wundschmerzen des Patienten führen, insbesondere da der

flüssige Wirkstoff in der Regel nicht die Körpertemperatur des Patienten aufweist.

Während der Unterdruckphase können sich unter Umständen die Poren der komprimierten Einlage 12 verkleben. Ein solches Verkleben behindert das Einfließen des Wirkstoffes allein durch die Schwerkraft, die sich aus der Höhe des Infusionsbehälters 24 gegenüber der Wunde 10 ergibt. Solche eventuellen Verklebungen der Poren können freigespült werden, indem beim Öffnen des Absperrorgans 32 zunächst ein gewisses Volumen des flüssigen Wirkstoffs unter Druck eingeleitet wird. Hierzu kann ein entsprechendes Volumen des Wirkstoffes mittels einer Kolbenspritze über die Zuleitung 22 eingeleitet werden. Die Kolbenspritze wird dabei zweckmäßigerweise an die Zuleitung 22 angeschlossen, wozu beispielsweise ein Dreiwegehahn in die Zuleitung 22 eingesetzt werden kann, an welchen die Kolbenspritze angeschlossen ist.

Sobald sich die Einlage 12 mit dem flüssigen Wirkstoff vollgesogen hat, wird zum Zeitpunkt t_2 das Absperrorgan 32 der Zuleitung 22 geschlossen. Für ein Einwirkungs-Zeitintervall T_2 bleiben nun die Absperrorgane 32 und 34 der Zuleitung 22 und der Ableitung 26 geschlossen, so daß der in der Einlage 12 enthaltene Wirkstoff auf die Oberfläche der Wunde 10 einwirken kann. Die Dauer des Einwirkungs-Zeitintervalls T_2 kann der Steuerung 36 vorgegeben werden und bestimmt sich nach der Art und dem Zustand der Wunde 10 und nach Art und Konzentration des Wirkstoffes. Wenn der Wirkstoff in dem Zeitintervall T_2 ausreichend auf die Wundoberfläche eingewirkt hat, wird zum Zeitpunkt t_3 das Absperrorgan 34 der Ableitung 26 geöffnet. Dadurch wird über den über die Anschlußleitung 30 anstehenden Unterdruck der flüssige Wirkstoff über den Drainageschlauch 16 (in Figur 1) bzw. den Drainageschlauch 18 (in Figur 2) aus der Einlage 12 und der Wunde 10 abgesaugt. Gleichzeitig wird die Wundflüssigkeit abgesaugt, die sich in dem Einwirkungs-Zeitintervall T_2 in der Wunde 10 angesammelt hat und durch die Einwirkung des Wirkstoffes erzeugte Zerfalls- und Zersetzungsprodukte enthält.

Das Öffnen des Absperrorgans 34 wird mittels der Steuerung 36 zeitlich so gesteuert, daß sich der Durchtrittsquerschnitt der Ableitung 26 nur langsam öffnet und der Unterdruck in der Einlage 12 und der Wunde 10 nur langsam zunimmt, wie dies in Figur 3 durch die ausgezogene Linie gezeigt ist. Ein sofortiges vollständiges Öffnen des Absperrorgans 34 würde zu einem sehr steilen Druckabfall im Bereich der Wunde führen, wie dies in Figur 3 strichpunktiert gezeichnet ist, was mit Wundschmerzen für den Patienten verbunden wäre.

Ist zum Zeitpunkt t_4 der ursprüngliche Unterdruck wieder erreicht, was gegebenenfalls durch den Drucksensor 38 überwacht werden kann, so ist der flüssige Wirkstoff wieder vollständig aus der Wunde 10 und der Einlage 12 entfernt. Der Unterdruck wird nun über ein Unterdruck-Zeitintervall T_4 aufrechterhalten. Dabei wird in der Regel das Absperrorgan 34 geöffnet bleiben, so daß der Unterdruck kontinuierlich durch die Unterdruckquelle 30 aufrechterhalten wird und das entstehende Wundsekret in den Auffangbehälter 28 kontinuierlich abgesaugt wird. Es ist auch möglich, das Absperrorgan 34 zu schließen oder zeitweise zu schließen und nur kurzzeitig zu öffnen, wenn der durch den Drucksensor 38 überwachte Unterdruck regeneriert werden muß.

Soll die nächste Behandlung der Wunde 10 mit einem flüssigen Wirkstoff erfolgen, so wird zum Zeitpunkt t_1 das Absperrorgan 34 geschlossen und das Absperrorgan 32 der Zuleitung 22 wieder geöffnet, so daß der beschriebene Zyklus wieder von vorn beginnt.

Anstelle der in den Figuren 1 und 2 gezeigten elektromagnetisch, pneumatisch oder hydraulisch betätigten Schlauchklemmen 32 und 34 können die Absperrorgane für die Zuleitung 22 und die Ableitung 26 auch als Mehrwegehähne ausgebildet sein. Entsprechende Ausführungsbeispiele sind in den Figuren 4 bis 8 gezeigt. Die Ausbildung der Absperrorgane als Mehrwegehähne ergibt einen einfachen Aufbau und ein zuverlässiges Schalten der Absperrorgane. Insbesondere ergibt sich eine einfache Steuerung der Absperrorgane, wenn die Mehrwegehähne mittels elektrischer Schrittmotoren geschaltet werden, was in einfacher Weise durch Antrieb der Hahnküken über die jeweiligen Schrittmotoren erfolgt. Das Schalten der Mehrwegehähne über Schrittmotore erlaubt eine einfache elektronische Steuerung. Diese Steuerung kann in einfacher Weise und mit großer Flexibilität programmiert werden, um eine Anpassung an den gewünschten Behandlungszyklus zu erreichen. Die Steuerung und der Behandlungszyklus können auf diese Weise individuell für jeden Patienten und jede Indikation programmiert werden Auch das Öffnen und Schließen der Mehrwegehähne kann mittels der Schrittmotore elektronisch genau und flexibel zeitlich gesteuert werden, um den in Figur 3 gezeigten Druckverlauf zu realisieren.

In den Figuren 4 bis 8 sind jeweils nur die Absperrorgane der Vorrichtung gezeigt. Im übrigen entspricht die Vorrichtung den Ausführungsbeispielen der Figuren 1 und 2.

In dem Ausführungsbeispiel der Figur 4 ist nur ein Drainageschlauch 16 vorgesehen. Die Zuleitung 22 und die Ableitung 26 sind alternativ über einen Dreiwegehahn 38 mit dem Drainageschlauch 16 verbindbar. Mittels der elektronischen Steuerung 36 wird programmierbar ein nicht dargestellter Schrittmotor gesteuert, der den Dreiwegehahn 38 betätigt. In der Stellung a ist die Zuleitung 22 über den Dreiwegehahn 38 an den Drainageschlauch 16 angeschlossen, so daß der Wirkstoff in die poröse Einlage 12 eingeleitet werden kann. Anschließend wird der Dreiwegehahn 38 in die Stellung b gedreht, in welcher der Drainageschlauch 16 gesperrt ist, um den eingeleiteten Wirkstoff auf die Wunde einwirken zu lassen. Zum Absaugen wird der Dreiwegehahn 38 in die Stellung c gedreht, in welcher der Drainageschlauch 16 an die Ableitung 26 angeschlossen ist.

Das Ausführungsbeispiel der Figur 5 zeigt die Vorrichtung mit einem Drainageschlauch 16 für die Zuleitung und einem Drainageschlauch 18 für das Absaugen. Sowohl in die Zuleitung 22 als auch in die Ableitung 26 ist jeweils ein Zweiwegehahn 40 bzw. 42 eingeschaltet, so daß sich die Funktionsweise ergibt, wie sie in dem Ausführungsbeispiel der Figur 2 beschrieben ist. In der Stellung a ist der Zweiwegehahn 40 geöffnet und der Zweiwegehahn 42 geschlossen, so daß die Zuleitung 22 an den Drainageschlauch 16 angeschlossen ist, während der Drainageschlauch 18 gesperrt ist. In dieser Stellung a wird der flüssige Wirkstoff über den Drainageschlauch 16 in die Einlage 12 eingeleitet. Anschließend wird der Zweiwegehahn 40 gesperrt, so daß die Stellung b eingenommen wird. Sowohl die Zuleitung 22 als auch die Ableitung 26 sind abgesperrt, so daß der von der Einlage 12 aufgenommene Wirkstoff einwirken kann. Nach Beendigung der Einwirkungsphase wird der Zweiwegehahn 42 geöffnet, entsprechend der Stellung c, so daß nun der Wirkstoff und eventuelles Sekret über den Drainageschlauch 18 und die Ableitung 26 abgesaugt werden können. Nach einem mehr oder weniger langen Unterdruck-Intervall wird erneut in die Stellung a umgeschaltet, um wiederum einen Behandlungswirkstoff zuzuführen.

Die Ausführung der Figur 6 entspricht funktionsmäßig dem Ausführungsbeispiel der Figur 5. Es sind lediglich anstelle der zwei Zweiwegehähne 40 und 42 ein Vierwegehahn 44 vorgesehen. Der Vierwegehahn 44 verbindet in Stellung a die Zuleitung 22 mit dem Drainageschlauch 16, sperrt in Stellung b sowohl die Zuleitung 22 als auch die Ableitung 26 und verbindet in Stellung c die Ableitung 26 mit dem Drainageschlauch 18.

Bei den bisher beschriebenen Ausführungen ist jeweils nur eine Zuleitung 22 vorgesehen, so daß nur ein Infusionsbehälter 24 angeschlossen werden kann. Sollen unterschiedliche Wirkstoffe zugeführt werden, so muß der mit der Zuleitung 22 konnektierte Infusionsbehälter 24 ausgewechselt werden. Ebenso muß der Infusionsbehälter 24 entfernt und gegen eine Kolbenspritze ausgetauscht werden, wenn die Einlage 12 im Falle von Verklebungen der Poren freigespült werden soll. Diese Nachteile können durch die Ausführungsbeispiele der Figuren 7 und 8 behoben werden.

Das Ausführungsbeispiel der Figur 7 entspricht insoweit dem Ausführungsbeispiel der Figur 1, als nur ein Drainageschlauch 16 für die Zuleitung und die Ableitung vorgesehen ist. Der Drainageschlauch 16 ist über zwei in Reihe angeordnete Dreiwegehähne 46 und 48 angeschlossen. Der erste Dreiwegehahn 46 schließt wahlweise eine erste Zuleitung 22.1 oder die Ableitung 26 an eine Verbindungsleitung zu dem zweiten Dreiwegehahn 48. Der zweite Dreiwegehahn 48 schließt wahlweise diese Verbindungsleitung oder eine zweite Zuleitung 22.2 an den Drainageschlauch 16 an. In der Stellung a verbindet der erste Dreiwegehahn 46 die erste Zuleitung 22.1 mit der Verbindungsleitung und der zweite Dreiwegehahn 48 diese Verbindungsleitung mit dem Drainageschlauch 16. Es kann über die erste Zuleitung 22.1 ein erster Wirkstoff eingeleitet werden. Die zweite Zuleitung 22.2 und die Ableitung 26 sind gesperrt. In Stellung b sperrt der erste Dreiwegehahn 46 sämtliche Anschlüsse, während der zweite Dreiwegehahn 48 die zweite Zuleitung 22.2 mit dem Drainageschlauch 16 verbindet. In dieser Stellung kann über die Zuleitung 22.2 ein zweiter Wirkstoff eingeleitet werden. In der Stellung c sperren beide Dreiwegehähne 46 und 48 sämtliche Zuleitungen, so daß die eingeleiteten Wirkstoffe über ein steuerbares Zeitintervall einwirken können. Anschließend wird in der Stellung d der Drainageschlauch 16 über den zweiten Dreiwegehahn 48 mit der Verbindungsleitung verbunden, während der erste Dreiwegehahn 46 die Verbindungsleitung mit der Ableitung 26 verbindet. Es können nun die Wirkstoffe und ein eventuelles Wundsekret aus der Einlage 12 über den Drainageschlauch 16 und die Ableitung 26 abgesaugt werden.

Die Ausführung der Figur 7 eignet sich auch dazu, zu Beginn der Einleitungsphase die Einlage 12 freizuspülen. In diesem Falle wird an die Zuleitung 22.1 eine Kolbenspritze angeschlossen, während an die Zuleitung 22.2 der Infusionsbehälter 24 angeschlossen wird. Zunächst wird in der Stellung a mittels der Kolbenspritze, die verklebte Einlage 12 freigespült, um dann in der Stellung b den Wirkstoff aus den Infusionsbehälter 22 durch Schwerkraft über die zweite Zuleitung 22.2 zuzuführen. Das Freispülen mittels einer Kolbenspritze kann somit durchgeführt werden, ohne daß die Konnektierung der Anschlüsse geändert werden muß.

In dieser Ausführung ist es auch möglich, den an der zweiten Zuleitung 22.2 angeschlossenen Infusionsbehälter 24 nur als Vorratsbehälter für den flüssigen Wirkstoff zu verwenden und diesen ausschließlich mittels der an der ersten Zuleitung 22.1 angeschlossenen Spritze zu applizieren. Hierzu wird der erste Dreiwegehahn 46 in die Stellung der Figur 7a gebracht, während der zweite Dreiwegehahn 48 gegenüber dieser Stellung so verdreht wird, daß er die zweite Zuleitung 22.2 mit der Verbindungsleitung zu dem ersten Dreiwegehahn 46 verbindet. Es kann nun der flüssige Wirkstoff aus dem an die Zuleitung 22.2 angeschlossenen Infusionsbehälter 24 über den ersten Dreiwegehahn 46 in die an der ersten Zuleitung 22.1 angeschlossene Kolbenspritze geleitet werden, um diese zu füllen. Sobald die Kolbenspritze gefüllt ist, wird der zweite Dreiwegehahn 48 in die Stellung der Figur 7a gebracht, so daß der flüssige Wirkstoff nun mittels der Kolbenspritze appliziert werden kann.

Figur 8 zeigt eine Ausführung, die wiederum im Prinzip der Ausführung der Figur 2 entspricht, bei welcher ein Drainageschlauch 16 für die Zuleitung und ein Drainageschlauch 18 für die Ableitung vorgesehen sind. Die Einleitung kann jedoch über zwei Zuleitungen 22.1 und 22.2 erfolgen. Es besteht somit auch hier die Möglichkeit über die Zuleitungen 22.1 und 22.2 zwei verschiedene Wirkstoffe zuzuführen oder über eine der

Zuleitungen den Wirkstoff über eine Spritze und über die andere Zuleitung den Wirkstoff aus einem Infusionsbehälter zuzuleiten. Der Drainageschlauch 16 ist über einen Dreiwegehahn 50 mit den beiden Zuleitungen 22.1 und 22.2 verbindbar, während der Drainageschlauch 18 über einen Zweiwegehahn 52 an die Ableitung 26 angeschlossen ist. In der Stellung a ist die erste Zuleitung 22.1 mit dem Drainageschlauch 16 verbunden, um einen ersten Wirkstoff zuzuleiten oder um die Einlage 12 freizuspülen. Der Zweiwegehahn 52 sperrt den zweiten Drainageschlauch 18. In der Stellung b wird ein zweiter Wirkstoff über die zweite Zuleitung 22.2 zugeleitet. In der Stellung c sind sowohl der Dreiwegehahn 50 als auch der Zweiwegehahn 52 für das Einwirken des Wirkstoffes gesperrt. In der Stellung d sperrt der Dreiwegehahn 50 sämtliche Anschlüsse, während der Zweiwegehahn 52 den Drainageschlauch 18 mit der Ableitung 26 verbindet, um die Wirkstoffe abzusaugen.

Auch hier kann an den Anschluß 22.2 ein Infusionsbehälter 24 angeschlossen werden, der nur als Vorratsbehälter für den flüssigen Wirkstoff verwendet wird, während dieser flüssige Wirkstoff mittels einer an die Zuleitung 22.1 angeschlossenen Spritze appliziert wird. In einer zu der Stellung b um 180° gedrehten Stellung verbindet dabei der Dreiwegehahn 50 den an die Zuleitung 22.2 angeschlossenen Vorrats-Infusionsbehälter 24 mit der an die Zuleitung 22.1 angeschlossenen Kolbenspritze, um diese zu füllen.

Patentansprüche

1. Vorrichtung zur Applikation von Wirkstoffen an einer Wundoberfläche, mit einer Einlage aus einem porösen Material zum Auflegen auf die Wundoberfläche, mit einer abdichtenden Auflage zum Überdekken der Wundoberfläche und der Einlage, die abdichtend an der Hautoberfläche befestigbar ist, mit wenigstens einer in die Einlage führenden Zuleitung für einen flüssigen Wirkstoff und mit wenigstens einer in die Einlage führenden Ableitung, die an eine Unterdruckquelle anschließbar ist, dadurch gekennzeichnet, daß die Zuleitung (22; 22.1, 22.2) ein steuerbares Absperrorgan (32; 38; 40; 44; 46; 48; 50) aufweist, daß die Ableitung (26) ein steuerbares Absperrorgan (34; 38; 42; 44; 46; 48; 52) aufweist und daß eine Steuerung (36) vorgesehen ist, die diese Absperrorgane (32; 34; 38; 40; 42; 44; 46; 48; 50; 52) zeitlich so steuert, daß das Absperrorgan (32; 34; 38; 40; 42; 44; 46; 48; 50; 52) der Zuleitung (22; 22.1, 22.2) und das Absperrorgan (34; 38; 40; 42; 44; 46; 48; 52) der Ableitung (26) nicht gleichzeitig sich überlappend geöffnet sind und daß zwischen dem Schließen des Absperrorgans (32; 34; 38; 40; 42; 44; 46; 48; 50; 52) der Zuleitung (22; 22.1, 22.2) und dem Öffnen des Absperrorgans (34; 38; 40; 42; 44; 46; 48; 50; 52) der Ableitung (26) ein Einwirkungs-Zeitintervall (T_2) geschaltet ist.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Einlage (12) aus einem elastisch kompressiblen porösen Material besteht.

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß die Einlage (12) aus einem offenporigen PVA-Schaumstoff besteht.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die abdichtende Auflage eine flexible Folie (14) ist, die luftdicht ist, jedoch die Diffusion von Wasserdampf zuläßt.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Zuleitung (22; 22.1, 22.2) und die Ableitung (26) über einen gemeinsamen Drainageschlauch (16) in die Einlage (12) führen.

6. Vorrichtung nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß die Zuleitung (22; 22.1, 22.2) und die Ableitung (26) jeweils über gesonderte Drainageschläuche (16 bzw. 18) in die Einlage (12) führen.

7. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Öffnungsvorgang des Absperrorgans (32; 34; 38; 40; 42; 44; 46; 48; 50; 52) der Zuleitung (22; 22.1, 22.2) mittels der Steuerung (36) zeitlich steuerbar ist.

8. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Öffnungsvorgang des Absperrorgans (34; 38; 40; 42; 44; 46; 48; 50; 52) der Ableitung (26) mittels der Steuerung (36) zeitlich steuerbar ist.

9. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Steuerung (36) nach dem Absaugen (T_3) ein Unterdruck- Zeitintervall (T_4) bestimmt, in welchem ein vorgegebener Unterdruck in der Einlage (12) aufrechterhalten wird.

10. Vorrichtung nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß ein Drucksensor (38) unter die abdichtende Auflage (14) einsetzbar ist, der mit der Steuerung (36) wirkungsmäßig verbunden ist.

11. Vorrichtung nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, daß die Absperrorgane (32, 34) elektromagnetisch, pneumatisch oder hydraulisch gesteuerte Schlauchklemmen sind.

12. Vorrichtung nach Anspruch 11, dadurch gekennzeichnet, daß die als Schlauch ausgebildete Zuleitung (22) bzw. Ableitung (34) in eine Aufnahme der Schlauchklemme (32) bzw. (34) einlegbar ist und

durch einen gesteuert betätigten Stempel gegen ein Widerlager quetschbar ist.

13. Vorrichtung nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, daß die Absperrorgane Mehrwegehähne (38; 40; 42; 44; 46; 48; 50; 52) sind.

14. Vorrichtung nach Anspruch 13, dadurch gekennzeichnet, daß die Mehrweghähne (38; 40; 42; 44; 46; 48; 50; 52) mittels durch die Steuerung (36) gesteuerter Schrittmotoren betätigbar sind.

15. Vorrichtung nach Anspruch 14, dadurch gekennzeichnet, daß die Steuerung (36) eine programmierbare elektronische Steuerung ist.

Fig. 1

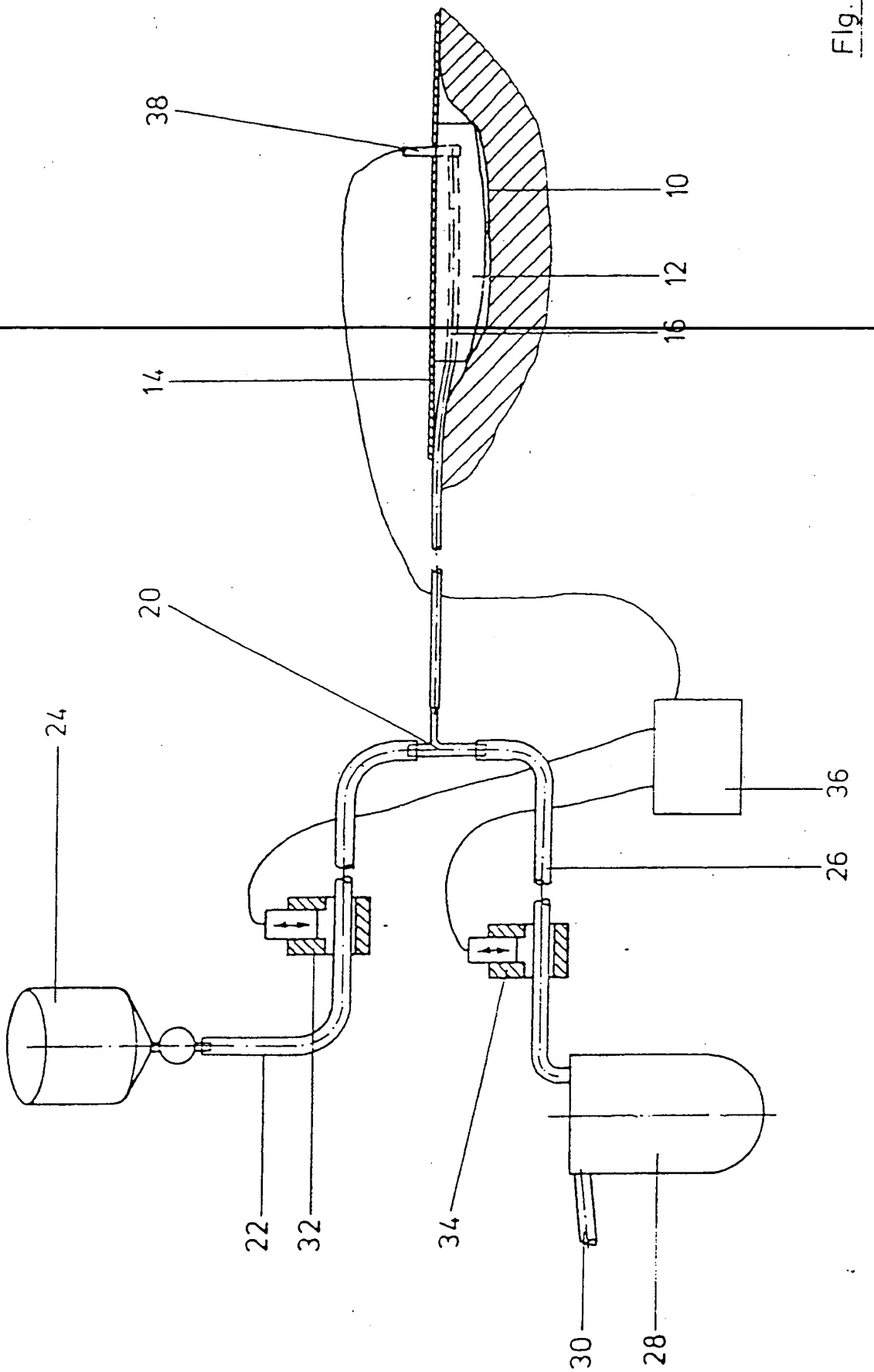
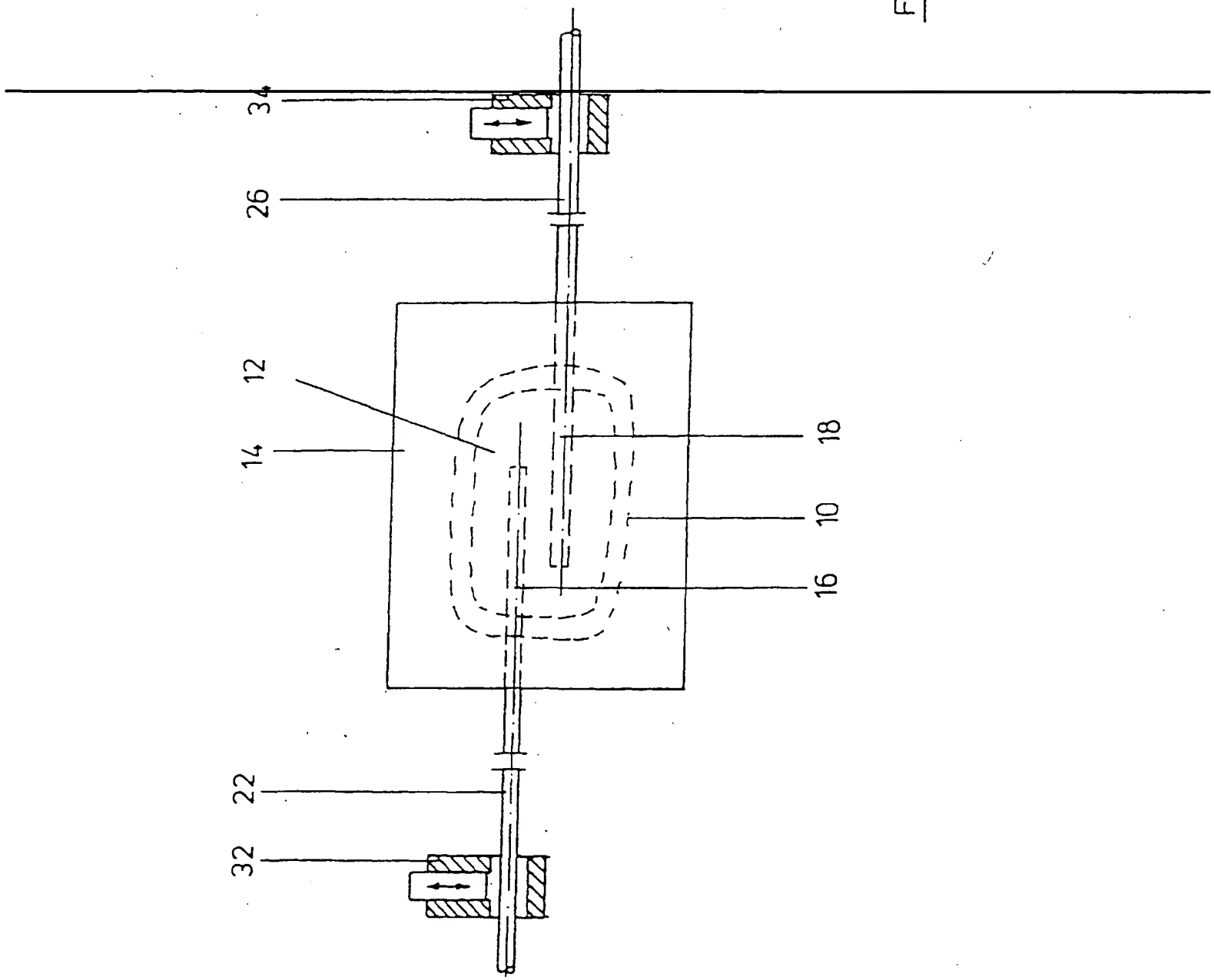


Fig. 2



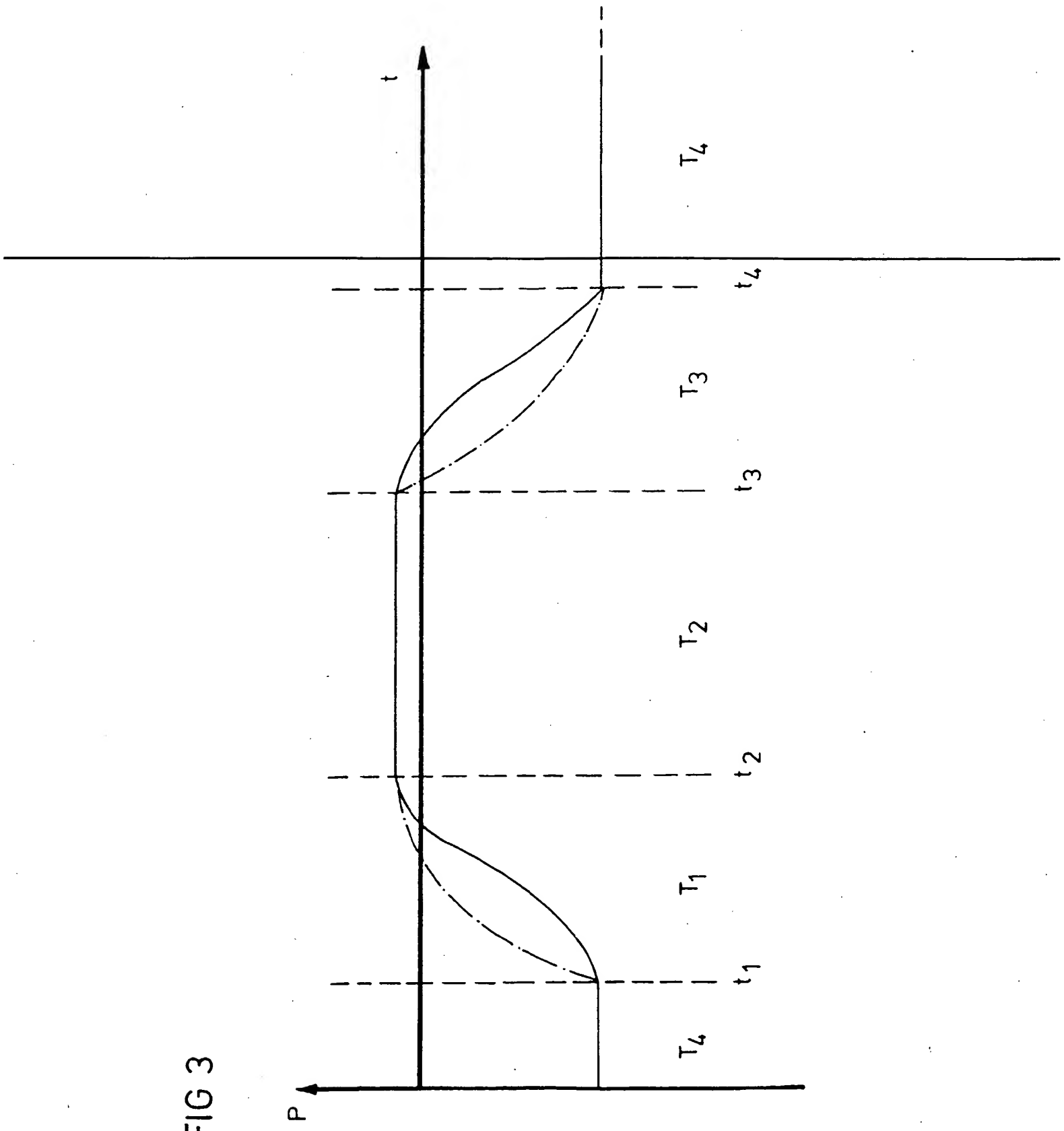


FIG 3

FIG 4 a) b) c)

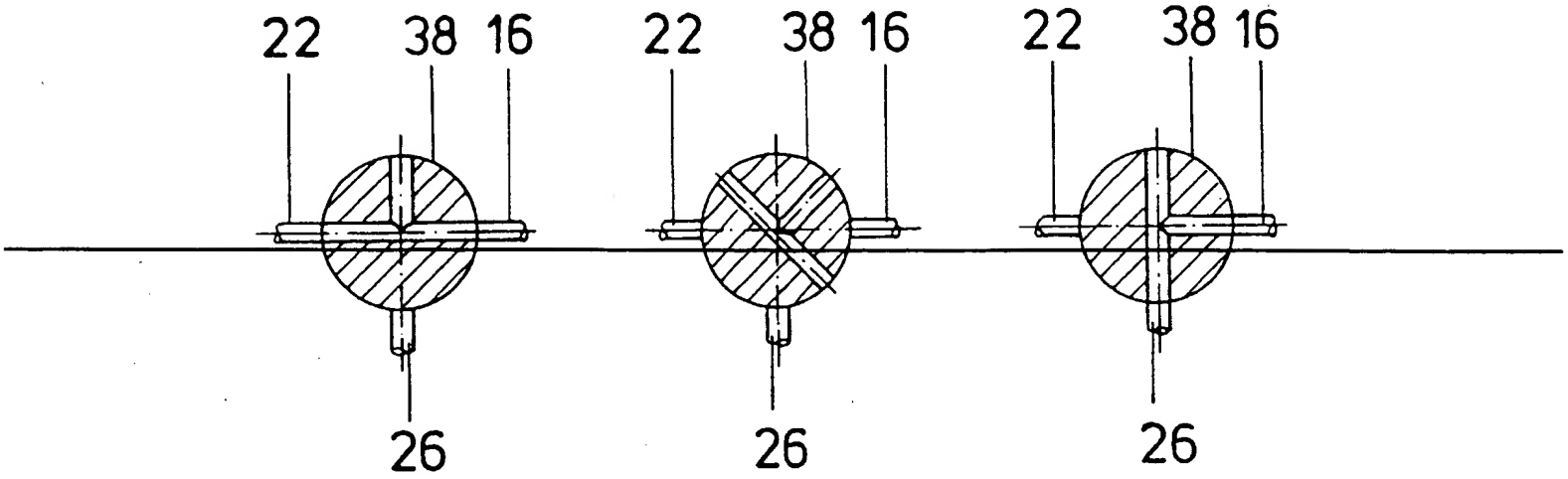


FIG 5 a) b) c)

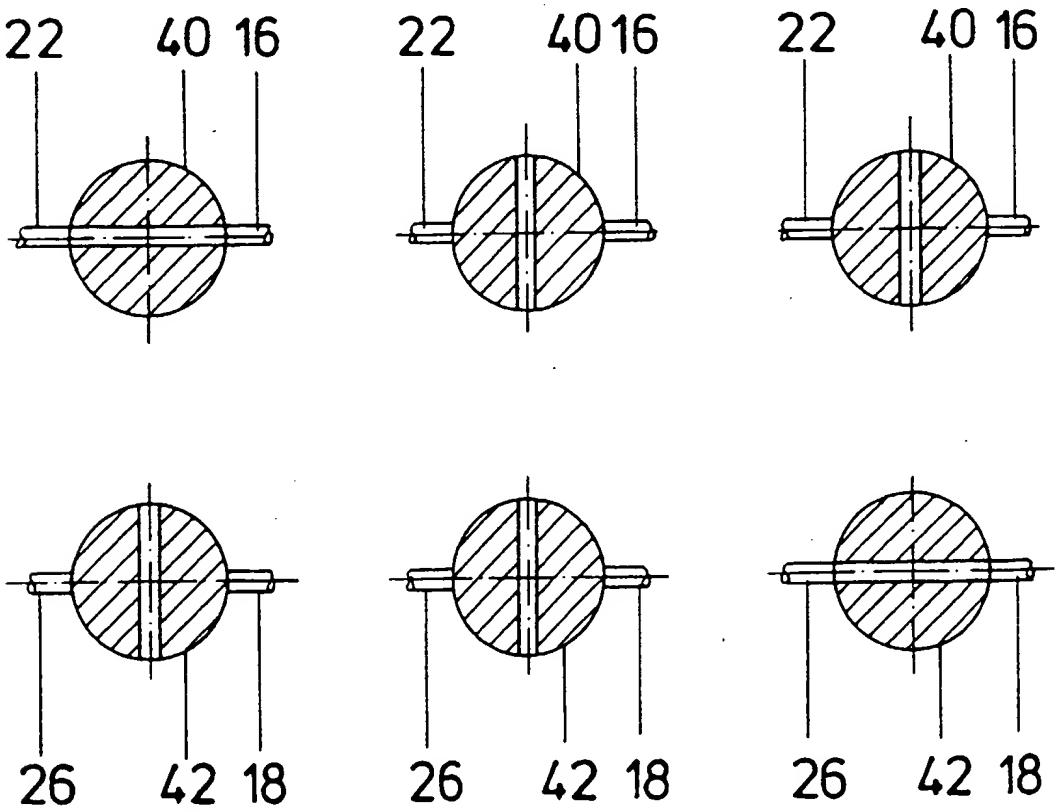


FIG 6 a) b) c)

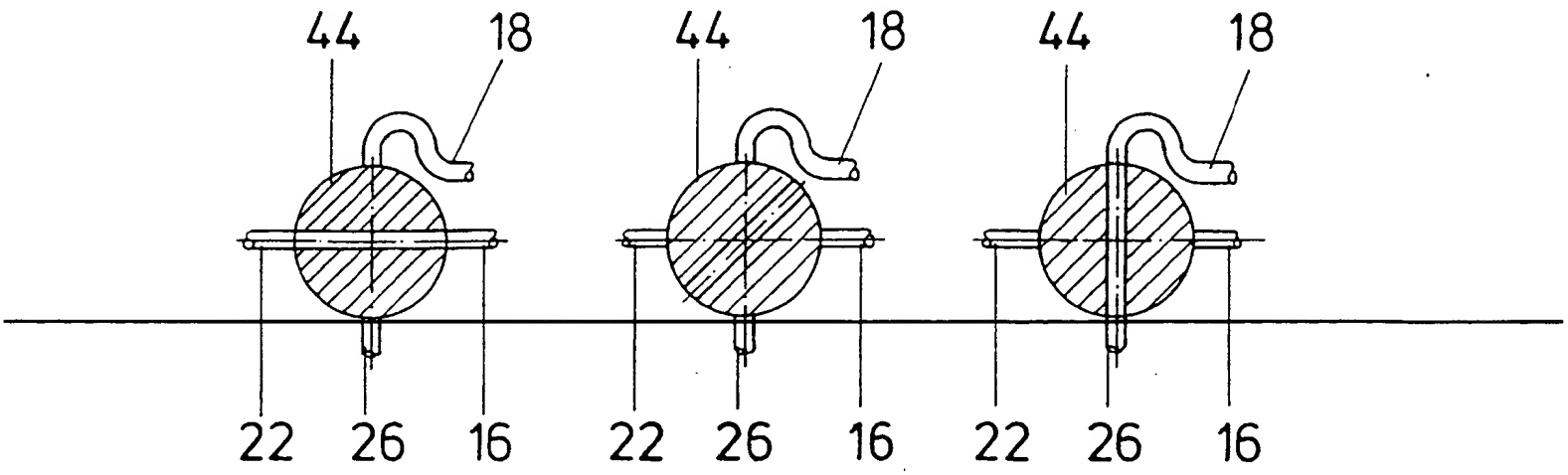
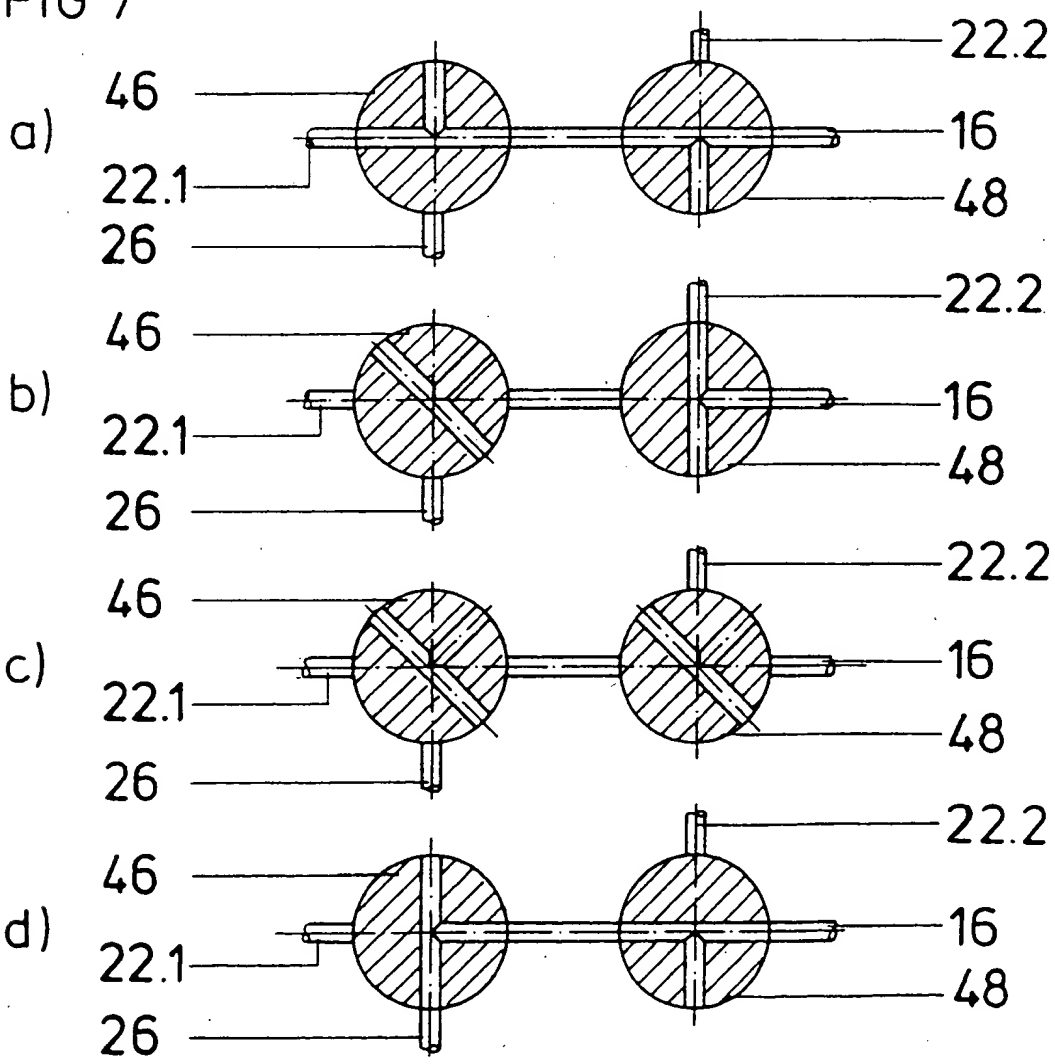


FIG 7



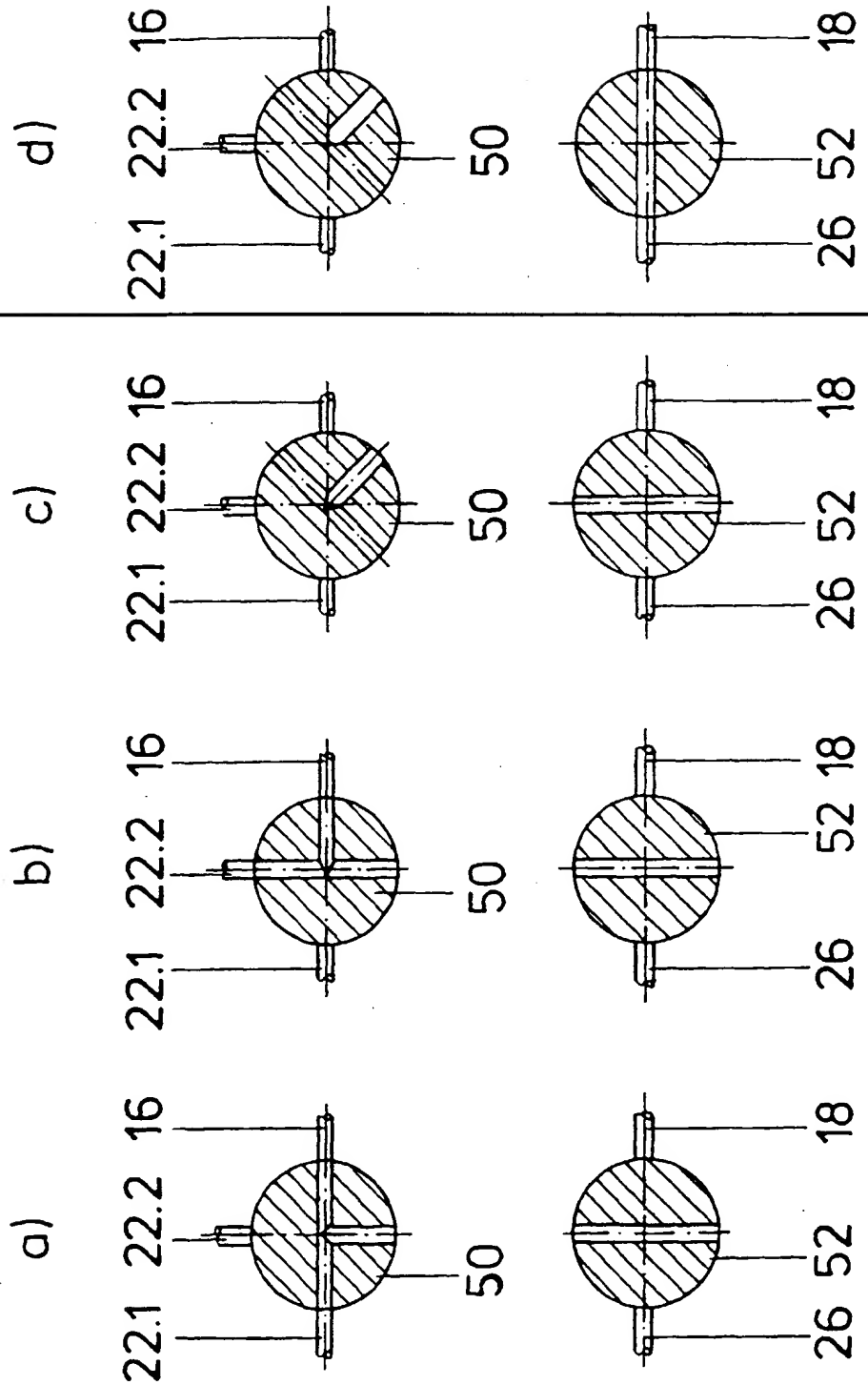


FIG 8

Express Mail No.: EL504450627US

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 7175-64836

Box No. I TITLE OF INVENTION

WOUND TREATMENT APPARATUS

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

HENLEY, Alan Wayne
196 Prestwick Court
Summerville, SC 29483
US

[X] This person is also inventor.

Telephone No. (812) 934-7000

Facsimile No. (812) 934-1633

Teleprinter No.

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: [X] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

MOSES, Leigh Marie
506 Pointe of Oaks Road
Summerville, SC 29485
US

This person is:

[ ] applicant only

[X] applicant and inventor

[ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: [X] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

[X] Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: [X] agent [ ] common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

NIEDNAGEL, Timothy E.
BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

Telephone No. (317) 236-1313

Facsimile No. (317) 231-7433

Teleprinter No.

[ ] Address for correspondence: Mark this check-box where no agent or common representative is has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

SANDERSON, Ronald Leslie
P.O. Box 70543
Charleston, SC 29514
US

This person is:
- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [x] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

HOWARD, John
415 Howle Avenue
Charleston, SC 29412
US

This person is:
- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [x] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

PRICE, James H.
1524 Strathmore Lane
Mount Pleasant, SC 29464
US

This person is:
- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [x] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BESSETTE, Russell W.
2157 Main Street
Buffalo, NY 14214
US

This person is:
- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [x] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

- [ ] Further applicants and or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

- ☒ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **SD** Sudan, **SL** Sierra Leone, **SZ** Swaziland, **UG** Uganda, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **GW** Guinea-Bissau, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☒ **AE** United Arab Emirates
- ☒ **AL** Albania
- ☒ **AM** Armenia
- ☒ **AT** Austria
- ☒ **AU** Australia
- ☒ **AZ** Azerbaijan
- ☒ **BA** Bosnia and Herzegovina
- ☒ **BB** Barbados
- ☒ **BG** Bulgaria
- ☒ **BR** Brazil
- ☒ **BY** Belarus
- ☒ **CA** Canada
- ☒ **CH and LI** Switzerland and Liechtenstein
- ☒ **CN** China
- ☒ **CU** Cuba
- ☒ **CZ** Czech Republic
- ☒ **DE** Germany
- ☒ **DK** Denmark
- ☒ **EE** Estonia
- ☒ **ES** Spain
- ☒ **FI** Finland
- ☒ **GB** United Kingdom
- ☒ **GD** Grenada
- ☒ **GE** Georgia
- ☒ **GH** Ghana
- ☒ **GM** Gambia
- ☒ **HR** Croatia
- ☒ **HU** Hungary
- ☒ **ID** Indonesia
- ☒ **IL** Israel
- ☒ **IN** India
- ☒ **IS** Iceland
- ☒ **JP** Japan
- ☒ **KE** Kenya
- ☒ **KG** Kyrgyzstan
- ☒ **KP** Democratic People's Republic of Korea
- ☒ **KR** Republic of Korea
- ☒ **KZ** Kazakhstan
- ☒ **LC** Saint Lucia
- ☒ **LK** Sri Lanka
- ☒ **LR** Liberia
- ☒ **LS** Lesotho
- ☒ **LT** Lithuania
- ☒ **LU** Luxembourg
- ☒ **LV** Latvia
- ☒ **MD** Republic of Moldova
- ☒ **MG** Madagascar
- ☒ **MK** The former Yugoslav Republic of Macedonia
- ☒ **MN** Mongolia
- ☒ **MW** Malawi
- ☒ **MX** Mexico
- ☒ **NO** Norway
- ☒ **NZ** New Zealand
- ☒ **PL** Poland
- ☒ **PT** Portugal
- ☒ **RO** Romania
- ☒ **RU** Russian Federation
- ☒ **SD** Sudan
- ☒ **SE** Sweden
- ☒ **SG** Singapore
- ☒ **SI** Slovenia
- ☒ **SK** Slovakia
- ☒ **SL** Sierra Leone
- ☒ **TJ** Tajikistan
- ☒ **TM** Turkmenistan
- ☒ **TR** Turkey
- ☒ **TT** Trinidad and Tobago
- ☒ **UA** Ukraine
- ☒ **UG** Uganda
- ☒ **US** United States of America
- ☒ **UZ** Uzbekistan
- ☒ **VN** Viet Nam
- ☒ **YU** Yugoslavia
- ☒ **ZA** South Africa
- ☒ **ZW** Zimbabwe

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

- ☒ **CR** Costa Rica
- ☐

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) (07.08.98) 07 August 1998	60/095,625	US		
item (2)				
item (3)				

XX The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): (1)

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):* ISA / EP

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):* Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	4
description (excluding sequence listing part)	25
claims	6
abstract	1
drawings	21
sequence listing part of description	0
Total number of sheets	57

This international application is **accompanied** by the item(s) marked below:

1. XX fee calculation sheet
2. XX separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. XX other *(specify)*: Transmittal Letter to the US/RO Return Postal Card

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Timothy E. Niednagel

Timothy E. Niednagel, Agent for Applicants

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PCT

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s) :
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

HENLEY, Alan Wayne
196 Prestwick Court
Summerville, SC 29483
US

hereby appoint(s) the following person as: [XX] agent [ ] common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

NIEDNAGEL, Timothy E.; COFFEY, William R.; CONARD, Richard D.; LAMMERT, Steven R.; REZEK, Richard A.; HARRISON, Nancy, J.; CARTER, R. Trevor; KULKARNI, Dilip A.; QUICK, David B.; POWLICK, Jill T.; HEDGES, Norman J.; PALAN, Perry; NEWMAN, Mark M.; GILLENWATER, Bobby B.; HUNT, Paul B.; GZYBOWSKI, Michael S.; GALLAGHER, Gerald T.; NULL, Robert D.; MARTIN, Alice O.; COOPER, Gregory S.; All Appointed Agents of the Address:

BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

to represent the undersigned before

[XX] all the competent International Authorities
[ ] the International Searching Authority only
[ ] the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

US as receiving Office

and to make or receive payments on behalf of the undersigned.

Signature(s) *(where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power)*:

Alan Wayne Henley
Alan Wayne HENLEY

Date: (13.09.99) 9 / 13 / 99
Day/ Month/ Year

Express Mail No.: EL504450627US

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 7175-64836

Box No. I TITLE OF INVENTION

WOUND TREATMENT APPARATUS

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

HILL-ROM, INC.
1069 State Route 46 East
Batesville, IN 47006-9167
US

☐ This person is also inventor.

Telephone No.
(812) 934-8649

Facsimile No.
(812) 934-1633

Teleprinter No.

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

HENLEY, Alan Wayne
196 Prestwick Court
Summerville, SC 29483
US

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

NIEDNAGEL, Timothy E.
BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

Telephone No.
(317) 236-1313

Facsimile No.
(317) 231-7433

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

MOSES, Leigh Marie
506 Pointe of Oaks Road
Summerville, SC 29485
US

This person is:
- [ ] applicant only
- [XX] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

SANDERSON, Ronald Leslie
P.O. Box 70543
Charleston, SC 29514
US

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

HOWARD, John
415 Howle Avenue
Charleston, SC 29412
US

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

PRICE, James H.
1524 Strathmore Lane
Mount Pleasant, SC 29464
US

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

[X] Further applicants and/or (further) inventors are indicated on another continuation sheet.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BESSETTE, Russell W.
2157 Main Street
Buffalo, NY 14214
US

This person is:

- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [x] the United States of America only [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:

- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:

- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:

- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

[ ] Further applicants and/or (further) inventors are indicated on another continuation sheet.

PCT

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s) :
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

HILL-ROM, INC.
1069 State Route 46 East
Batesville, IN 47006-9167
US

hereby appoint(s) the following person as: [X] agent [ ] common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

NIEDNAGEL, Timothy E.; COFFEY, William R.; CONARD, Richard D.; LAMMERT, Steven R.; REZEK, Richard A.; WOODBURN, Jill L.; HARRISON, Nancy, J.; CARTER, R. Trevor; KULKARNI, Dilip A.; QUICK, David B.; POWLICK, Jill T.; CHURCH, Steven A.; HEDGES, Norman J.; PALAN, Perry; NEWMAN, Mark M.; GILLENWATER, Bobby B.; HUNT, Paul B.; GZYBOWSKI, Michael S.; GALLAGHER, Gerald T.; NULL, Robert D.; MARTIN, Alice O.; COOPER, Gregory S.; All Appointed Agents of the Address:

BARNES & THORNBURG
11 South Meridian Street
Indianapolis, IN 46204
US

to represent the undersigned before

[X] all the competent International Authorities

[ ] the International Searching Authority only

[ ] the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

US as receiving Office

and to make or receive payments on behalf of the undersigned.

Signature(s) *(where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power):*

Mark R. Lindenmeyer, Secretary

Date: 3 May 1999
Day/ Month/ Year

M·H 57

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :
A61M 27/00

A1

(11) International Publication Number: WO 00/07653

(43) International Publication Date: 17 February 2000 (17.02.00)

(21) International Application Number: PCT/US99/17877

(22) International Filing Date: 6 August 1999 (06.08.99)

(30) Priority Data:
60/095,625 7 August 1998 (07.08.98) US

(71) Applicant *(for all designated States except US)*: HILL–ROM, INC. [US/US]; 1096 State Route 46 East, Batesville, IN 47006–9167 (US).

(72) Inventors; and

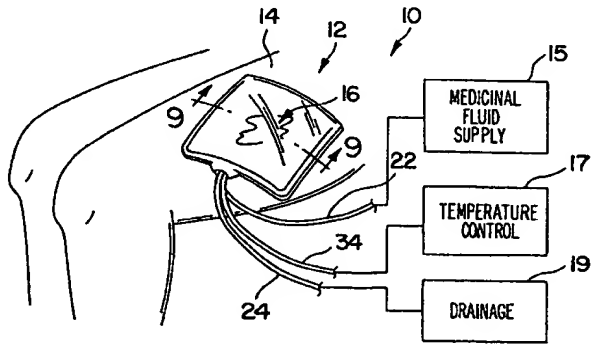
(75) Inventors/Applicants *(for US only)*: HENLEY, Alan, Wayne [US/US]; 196 Prestwick Court, Summerville, SC 29483 (US). MOSES, Leigh, Marie [US/US]; 506 Pointe of Oaks Road, Summerville, SC 29485 (US). SANDERSON, Ronald, Leslie [US/US]; P.O. Box 70543, Charleston, SC 29514 (US). HOWARD, John [US/US]; 415 Howle Avenue, Charleston, SC 29412 (US). PRICE, James, H. [US/US]; 1524 Strathmore Lane, Mount Pleasant, SC 29464 (US). BESSETTE, Russell, W. [US/US]; 2157 Main Street, Buffalo, NY 14214 (US).

(74) Agent: NIEDNAGEL, Timothy, E.; Barnes & Thornburg, 11 South Meridian Street, Indianapolis, IN 46204 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: WOUND TREATMENT APPARATUS



(57) Abstract

A wound treatment apparatus for treatment of surface wounds with a bandage system configured to control the environment adjacent the wound. The apparatus includes a bandage configured to cover a wound and provide a seal about the perimeter of the wound and cavity over the wound. A fluid supply conduit and a fluid drainage conduit are each in communication with the cavity. A nebulizer is coupled to the supply conduit to supply medicinal fluid to the wound. A waste receptacle is coupled to the drainage conduit to remove the fluid away from the wound.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

WOUND TREATMENT APPARATUS

Technical Field

The present invention relates to a wound treatment apparatus. More particularly, the present invention relates to a wound treatment apparatus for treatment of surface wounds.

Background Art

Medical professionals such as nurses and doctors routinely treat patients having surface wounds of varying size, shape, and severity. Variations in wound type and other patient indications dictate variations in desired medications for treatment, such as antibiotics, growth factors, enzymes, hormones, insulin, anesthetics, and the like. The nature of a wound further prescribes variations in treatment protocols, such as delivery rates for medication and temperature control.

It is known that controlling the topical atmosphere adjacent a surface wound can enhance the healing process of the wound, for example by manipulating the oxygen content and/or humidity, or by providing hyperbaric oxygen as part of a treatment protocol, or by introducing medicinal agents adjacent the wound surface. See, for example, Madalene C.Y. Heng, *Topical Hyperbaric Therapy for Problem Skin Wounds*, 19 J. DERMATOL. SURG. ONCOL. 784 (1993); Theodor Kaufman, M.D., et al., *The Microclimate Chamber: The Effect of Continuous Topical Administration of 96% Oxygen and 75% Relative Humidity on the Healing Rate of Experimental Deep Burns*, 23 J. TRAUMA 807 (1983); and U.S. Patent No. 4,969,881 to Viesturs, entitled "Disposable Hyperbaric Oxygen Dressing." The medical industry would benefit from a practical system for surface wound treatment that provides medical professionals with a flexible way to control the topical atmosphere adjacent the wound, including application of aerosol medications and atmospheric constituents such as oxygen, as well as providing for collection of drainage from the wound site.

Several publications establish that surgeons were active years ago in applying a bandage or cover over a wound to provide a vacuum space above the wound to enhance healing. Nevertheless, Wake Forest University inventors, while not

citing the publications, disclosed a vacuum wound therapy in U.S. Patents 5,645,081 and 5,636,643.

Conventional treatment of a surface wound typically involves placement of a packing or dressing material, such as cotton gauze, directly in contact with the patient's wound. Often there is a need to change the dressing material frequently because it becomes saturated with effluent material discharged from the wound. The frequency of the need to change the dressing can increase when the care giver applies fluids to the dressing such as a saline solution, peroxide, topical antibiotics, or other medicines dictated by various treatment protocols for different types of wounds.

Changing a wound dressing poses several potential problems for the care giver. Inadvertent contact with sensitive tissue within and adjacent the wound can cause significant discomfort to the patient as well as further trauma to the wound. Exposing the wound to the open atmosphere can increase the chance of infection. Dressings are typically secured in place with adhesives, and thus changing the dressing requires removing the adhesive from the patient's skin, posing risks of pain and trauma to the patient, especially if there is necrotic tissue. Similarly, the dressing material can bind with tissue within the wound, so that changing the dressing can cause tissue loss from the wound, resulting in pain to the patient and retarding the healing process. Medical care givers and patients both would benefit from a bandage system that provides sanitary collection and disposal of material discharged from a wound in the course of the treatment and healing process while reducing the need to remove dressing or packing material placed in contact with the wound.

Summary of the Invention

According to various features, characteristics, embodiments and alternatives of the present invention which will become apparent as the description thereof proceeds below, the present invention provides a wound treatment apparatus which includes a bandage configured to cover a wound and a seal about the perimeter of the wound. The bandage provides a cavity over the wound with a fluid supply and a fluid drainage in communication with the cavity. This cavity may be maintained at less than atmospheric pressure to enhance healing as known in the prior art. The present invention comprises enhancements to the prior art.

The wound treatment apparatus, for example, includes a first bandage configured to cover a wound. The first bandage includes a first surface configured to face toward the wound, at least one fluid delivery passageway through the first surface, at least one fluid drainage passageway through the first surface and fluid delivery conduit in communication with the fluid delivery passageway. The apparatus also includes a second bandage coupled with the first bandage. The second bandage includes a second surface configured to face toward the first bandage and provide a fluid space between the surfaces and has a fluid drainage conduit in communication with the fluid drainage passageway.

Another embodiment of the wound treatment apparatus includes a bandage including a wound facing surface configured to face toward the wound and a fluid drainage passageway having an opening adjacent the wound facing surface. A fluid drainage tube is coupled to the fluid drainage passageway. First and second fluid drainage receptacles are coupled to the drainage tube. First and second valves are coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively.

An additional embodiment of the wound treatment apparatus includes a cover bandage configured to cover a wound and provide a seal on healthy skin tissue about the perimeter of the wound. The cover provides a relatively closed space about the wound which may be held at negative pressure. A fluid supply conduit is fitted between the cover bandage and healthy skin tissue near the wound. A fluid drainage conduit having at least one fluid drainage opening is fitted between the cover bandage and the healthy skin tissue and positioned on healthy skin tissue about the wound and the fluid supply.

A further embodiment of the wound treatment apparatus includes a cover bandage providing a closed seal about a wound and a relatively closed cavity over the wound to be held at a negative pressure. The cover bandage includes a first surface configured to face toward the wound having least one fluid delivery passageway disposed through the first surface, and at least one fluid drainage passageway disposed through the first surface. A second surface is configured to face toward the first surface and provide a fluid space between the surfaces. The fluid space is segregated into a first chamber and a second chamber, wherein the first

chamber is formed about the fluid delivery passageway and the second chamber is formed about the fluid drainage passageway. A fluid delivery conduit is in fluid communication with the first chamber and the fluid delivery passageway. A fluid drainage conduit has at least one fluid drainage opening in fluid communication with the second chamber and the fluid drainage passageway.

A still further wound treatment apparatus includes a cover bandage providing a closed seal about a wound positioned on a joint having a cavity over the wound sized to receive the joint and to be held at a negative pressure. The cover bandage includes a first surface configured to face toward the wound, at least one fluid delivery passageway through the first surface, and a second surface configured to face toward the first surface providing a fluid space between the surfaces. A fluid delivery conduit is in fluid communication with the fluid space and the fluid delivery passageway. A fluid drainage conduit having at least one fluid drainage opening is also in fluid communication with the cavity.

Within the present invention, in combination with such a cover bandage, the fluid delivery to the wound may include nebulizers, liquid medication pumps, recirculating temperature regulated fluid tubes, heaters, temperature and pressure sensors, control valves, oxygen supplies, and controllers as described and claimed hereinafter. All of these features, including the vacuum feature, may be programmed to occur on prearranged schedules to deliver care-giver established protocols.

Additional features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description exemplifying the best mode of carrying out the invention as presently perceived.

Brief Description of the Drawings

The present invention will be described with reference to the attached drawings which are given as non-limiting examples only, in which:

Fig. 1 is a perspective view of a wound treatment apparatus according to the present invention;

Fig. 2 is a schematic block diagram of a wound treatment apparatus according to the present invention;

Fig. 3 is a schematic block diagram of an alternative embodiment wound treatment apparatus;

Fig. 4 is an exploded perspective view of a two-piece bandage assembly according to the present invention;

Fig. 5 is a top view of the bottom sheet of the medicinal delivery bandage of Fig. 4;

Fig. 6 is a top view of the top sheet of the medicinal delivery bandage of Fig. 4;

Fig. 7 is a top view of the medicinal fluid supply and temperature controlled, recirculating fluid tubes of Fig. 4;

Fig. 8 is an end view of the medicinal fluid supply and temperature controlled, recirculating fluid tubes of Fig. 7;

Fig. 9 is a sectional view taken along line 9—9 of Fig. 1;

Fig. 10 is a top view of the bandage assembly of Fig. 1 with portions broken away;

Fig. 11 is an exploded perspective view of an alternative embodiment of a bandage assembly;

Fig. 12 is a perspective view of another alternative embodiment of a bandage assembly;

Fig. 13 is a perspective view of yet another alternative embodiment of a bandage assembly;

Fig. 14 is an exploded perspective view of an alternative embodiment of a drainage bandage;

Fig. 15 is a diagrammatic perspective view of an alternative embodiment of a wound treatment apparatus;

Fig. 16 is a plan view of a recirculating fluid path assembly from the heating assembly of Fig. 15;

Fig. 17 is a perspective view of the fluid path assembly of Fig. 16;

Fig. 18 is an exploded perspective view of the radiant heating plate of the heating assembly of Fig. 15;

Fig. 19 is a system block diagram of an alternative drainage system embodiment;

Fig. 20 is an exploded view of a wound treatment assembly and a medicinal fluid supply system including an additional embodiment of the present invention;

Fig. 21 is a top view of the wound treatment assembly from Fig. 20;

Fig. 22 is a sectional view of the circulating fluid tube from the wound treatment assembly of Fig. 20, taken along line A-A;

Fig. 23 is a top view of a wound treatment assembly including another embodiment of the present invention;

Fig. 24 is a sectional view of the wound treatment assembly from Fig. 23, taken along line B-B;

Fig. 25 is a top view of a wound treatment assembly in accordance with a still further embodiment of the present invention;

Fig. 26 is a sectional view of the wound treatment assembly from Fig. 25, taken along line C-C;

Fig. 27 is a top view of a wound treatment assembly in accordance with an additional embodiment of the present invention;

Fig. 28 is a sectional view of the wound treatment assembly from Fig. 27, taken along line D-D;

Fig. 29 is a sectional view of the wound treatment assembly from Fig. 27, taken along line E-E;

Fig. 30 is a top view of a flexible wound treatment assembly in accordance with the present invention;

Fig. 31 is a sectional view of the flexible wound treatment assembly from Fig. 30, taken along line F-F; and

Fig. 32 is a sectional view of the flexible wound treatment assembly from Fig. 31, applied over a wound on a bendable joint.

Fig. 33 is a perspective view of a wound treatment apparatus including a heating system.

Fig. 34 is a perspective clear view of a portion of the wound treatment apparatus from Fig. 33.

Detailed Description of Drawings

Referring now to the drawings, Fig. 1 illustrates a wound treatment apparatus 10 that includes a bandage assembly 12 coupled to a patient's skin 14 adjacent a surface wound 16. Apparatus 10 includes a wound temperature control system 17, a wound drainage system 19, and a medicinal fluid supply system 15 including a nebulizer 26. Wound treatment apparatus 10 provides a system for controlling the topical atmosphere adjacent wound 16, including delivery of medication, control of atmospheric constituents, temperature regulation, and collection of wound drainage.

Including a nebulizer 26 (see Figs. 2 and 3) in wound treatment apparatus 10 provides for delivering nebulized fluid containing dissolved wound treatment constituents, such as oxygen or medication, to the wound. As a wound heals it develops a liquid layer on its external surface. This liquid layer forms a barrier that impedes flow of atmospheric constituents, such as oxygen or medication, to the cells in the wound, because these constituents must diffuse through the liquid layer. Application of nebulized fluid improves treatment and healing because the nebulized fluid can readily mix with the liquid layer. This allows the dissolved constituents in the nebulized fluid to be readily diffused through the liquid layer and absorbed into the cells below.

Bandage assembly 12 is a two-part assembly that includes a fluid medication delivery bandage 18 and an adsorbent drainage bandage 20. Drainage bandage 20 is configured to be removably coupled to delivery bandage 18 as shown, for example, in Figs. 2 and 3. Delivery bandage 18 provides for sealing the wound site from the ambient atmosphere so that supply system 15, temperature control system 17, and drainage system 19 can regulate the wound environment. By providing a two-piece, removably coupled bandage arrangement, bandage assembly 12 allows for changing the drainage bandage without the need to remove delivery bandage 18 from the patient's skin 14.

Delivery bandage 18 includes a medicinal fluid supply tube 22 and is coupled to the patient's skin 14 over wound 16. Delivery bandage 18 can remain in place while drainage bandage 20 can be changed as needed during wound treatment. Drainage bandage 20 includes a wound drainage tube 24 that is coupled to wound 16

through delivery bandage 18 to allow fluid from wound 16 to exit from bandage assembly 12, the fluid including both fluids secreted by wound 16 as well as fluids entering bandage 18 through medicinal fluid supply tube 22. Bandage assembly 12 thus allows control of the topical atmosphere adjacent wound 14 while limiting the exposure to atmospheric contaminants, allowing for use of treatment protocols to enhance healing while reducing opportunities for potential infection and trauma.

Medicinal fluid supply system 15 of wound treatment apparatus 10 illustratively includes nebulizer 26 and an optional liquid medication pump 39 as shown in Figs. 2 and 3. Temperature control system 17 includes a heater 40 and pump 42. Drainage system 19 includes a drainage bag 92 as shown in Fig. 2 or alternatively a vacuum pump 98 and liquid trap bottle 96 as shown by 19' in Fig. 3.

Nebulizer 26 includes an input port 28 for accepting a nebulizer gas input, such as standard air or pure oxygen, a nebulized fluid output port 30, and a liquid reservoir 32 coupled between input and output ports 28, 30. Liquid reservoir 32 illustratively contains medication as needed to implement a treatment protocol for wound 16, such as antibiotics, growth factors, enzymes, hormones, insulin, anesthetics, and the like. It is understood that reservoir 32 can contain any fluid, such as pure water or a saline solution. Nebulizer 26 is illustratively a Mini Heart model manufactured by Vortran, which can atomize approximately 4 milliliters per hour of liquid medication at an input gas flow rate of approximately 1.5 liters per minute. It is understood, however, that any suitable nebulizing device can be used.

Nebulizer output port 28 is coupled to medicinal fluid supply tube 22 of delivery bandage 18 of bandage assembly 12. Optionally, a liquid medication pump 39 such as an IV pump can also be coupled to medicinal fluid supply tube 22. Wound treatment apparatus 10 thus provides for delivery of either aerosol or liquid medication or both to wound 16 through delivery bandage 18.

As discussed in more detail below, delivery bandage 18 further includes a recirculating fluid tube 34 having an input port 36 and an output port 38. Wound treatment apparatus 10 includes a heater 40 and a peristaltic pump 42 coupled between the input and output ports 36, 38 of recirculating fluid tube 34. Temperature control system 17 thus allows temperature controlled liquid to flow through bandage assembly 12 to regulate the temperature at the site of wound 16.

Peristaltic pump 42 is illustratively a Model 313 manufactured by Watson Marlow, using a nominal flow rate of between 200 to 250 milliliters per minute. Although a peristaltic pump driven by an AC synchronous motor at 72 RPM is used because its disposable tubing elements eliminate the need to clean the pump between patient uses, it is understood that other pump designs such as centrifugal, gear-driven, or diaphragm type pumps can be used.

Heater 40 illustratively is a specially designed tubular unit that includes a tubular housing 37, a 100 watt heater element 35 positioned within housing 37, and a thermocouple 33 for monitoring the temperature of heater element 35. A fluid reservoir 41 is configured to fit within housing 37 so that heater element 35 can heat the recirculating fluid. As discussed below, other suitable heating systems can be used.

Fluid reservoir 41 illustratively is formed from a rubber silicone tube configured to fit snugly within housing 37. Reservoir 41 advantageously is provided as a prepackaged unit with bandage assembly 12 along with associated tubes to prevent spillage that can accidentally occur if an open container is used for the recirculating fluid. It is understood, however, that other suitable devices for controlling the temperature of the recirculating fluid can be used, such as an immersion heater configured to be placed within an open fluid reservoir (not shown), or alternative embodiment heating assembly 200 as shown in Figs. 14-18 and discussed in detail below.

Wound treatment apparatus 10 further includes a computer-based electronic control system 44 that is coupled electronically to the electronic and electro-mechanical components such as nebulizer 26, peristaltic pump 42, heater 40 and thermocouple 33. Control system 44 provides for automated control of wound treatment apparatus 10 for various treatment protocols, for example to regulate temperature at the wound site by using heater 40 and pump 42 to regulate recirculating fluid temperature to 37° Celsius.

Control system 44 illustratively is directly coupled to the controlled components using analog, discrete, and serial I/O signals as required by the various component interfaces. It is understood that the communication mechanism can include any type of electronic network, such as any serial bus or parallel bus architecture. The communications protocol similarly can vary. For example, master-slave, token ring, or

peer-to-peer communication protocols, such as Ethernet or Echelon LONworks™, can be used. By providing software control of wound treatment apparatus 10 components such as nebulizer 26, heater 40, and pump 42, control system 44 can automatically control the delivery of aerosol medication, temperature, and oxygen concentration levels at the site of wound 16 to implement a desired treatment protocol and to provide an optimal wound healing environment.

Nebulizer input port 28 is coupled to a nebulizer gas input assembly 46 that includes air and oxygen input ports 48, 50, an air compressor 52, air and oxygen pressure regulators 54, 56, a selector valve 58, and a nebulizer gas input filter 60. Filter 60 is illustratively a single use disposable bacteria filter.

Oxygen input port 48 can illustratively be coupled to a standard hospital oxygen blender 62 through a standard hospital air filter and water trap 64. An internal compressed oxygen supply (not shown) can replace oxygen blender 62. Oxygen filter and water trap 64 contains a 5 micron filter element and catch basin to trap particulate matter and condensed water output from oxygen blender 62. Blender 62 further illustratively includes an oxygen flowmeter 66 such as a standard hospital pediatric flowmeter that allows a flow set range of, for example, between zero and three liters per minute.

Air compressor 52 is coupled to nebulizer air input port 48 through an external air filter and water trap 68. Similar to supply of oxygen, an external compressed air supply (not shown) can also be used. Air compressor 52 is illustratively a diaphragm type pump driven by a brushless DC motor that can deliver a minimum of 1.3 liters per minute at 15 psi. Compressor 52 includes an input filter (not shown) having a 25 micron filter/silencer. Similar to oxygen filter and water trap 64, air filter and water trap 68 contains a 5 micron filter element and catch basin for trapping particulate matter and water droplets from the compressed air output from compressor 52.

Air and oxygen input ports 48, 50 are coupled to selector valve 58 through air and oxygen pressure regulators 54, 56, respectively. Regulators 54, 56 maintain air and oxygen pressure between about 15 and about 17 psi. Air pressure regulator 54 vents excess air outside of wound treatment apparatus 10 through an air vent 70 and oxygen pressure regulator vents through oxygen vent 72.

Selector valve 58 is coupled electronically to control system 44 to allow for software control of the mixing of air and oxygen so that the gas input to nebulizer 26 can range from pure air to pure oxygen. Selector valve 58 can eliminate the need for external oxygen blender 62. Selector valve 58 illustratively switches between air and oxygen at a predetermined rate, although other valve arrangements can be used to mix air and gas, such as a dual input mixing valve, a pair of butterfly valves or other valve configurations for mixing two fluid input streams. Control system 44 can be used to supply an air/oxygen treatment protocol to the wound site automatically. For instance, control system 44 can implement a programmed protocol to deliver 3 hours of air followed by 3 hours of oxygen, and so on, to the wound site. Valve 58 automatically switches to implement the programmed protocol.

Nebulizer gas input assembly 46 further includes an air pressure sensor 68 coupled between selector valve 58 and air pressure regulator 54, an oxygen pressure sensor 74 coupled between selector valve 58 and oxygen pressure regulator 56, and a nebulizer gas input pressure sensor 76 coupled between selector valve 58 and nebulizer input port 28. Sensors 72, 74, 76 are coupled to control system 44 to provide feedback for monitoring of proper system operation and so that an alarm can be indicated and wound treatment apparatus 10 shut down automatically if a pressure signal exceeds a predetermined threshold.

Wound treatment apparatus 10 also includes a nebulizer empty sensor 78 to indicate if nebulizer 26 is empty. Nebulizer empty sensor 78 provides a feedback signal to electronic control system 44 and illustratively is an acoustical sensor. Control system 44 continuously monitors the output signal from sensor 78, which changes distinctively when reservoir 32 becomes empty, at which point an alarm can be signaled and wound treatment apparatus 10 shut down. It is understood that other types of sensors can be used to determine if nebulizer 26 is empty, such as, for example, capacitive sensors, float switches, or optical, infrared, or ultrasonic sensors.

Wound treatment apparatus 10 further includes a nebulizer pressure sensor 80 coupled between selector valve 60 and nebulizer input port 28. Pressure sensor 80 provides a feedback signal to control system 44 indicative of pressure within nebulizer 26 and is also used to verify the proper operation of selector valve 60. Wound treatment apparatus 10 furthermore includes a tilt sensor 82 and a bandage

interface pressure sensor 84, both coupled to control system 44. Tilt sensor 82 signals an alarm and shuts down apparatus 10 if apparatus 10 is tilted beyond a predetermined threshold, illustratively 30°.

Bandage interface pressure sensor 84 is coupled between nebulizer output port 30 and medicinal fluid supply tube 22 of bandage assembly 12. By monitoring back pressure from the bandage, pressure sensor 84 allows control system 44 to provide a display indicative of pressure at the interface between delivery bandage 18 or between the patient and a bed when the patient is lying directly on bandage assembly 12. Control system 44 can also signal an alarm and shut down apparatus 10 if interface pressure exceeds a predetermined threshold.

Pressure on a wound can cause further skin breakdown, especially if the wound is a decubitus ulcer or bed sore. The wound interface pressure from sensor 84 can be used as a feedback signal to a bed control or a support surface control to adjust a therapy surface. Sensor output 84 can also signal the care giver through the control system and a nurse call system so that the care-giver can move the patient, either on the existing mattress or to a reduced pressure support surface, for treating the wound.

Temperature control system 17 includes heater 40, reservoir 41, and pump 42. Fluid reservoir 41 includes an input port 43 coupled to output port 38 of recirculating fluid tube 34 and an output port 45 coupled to a tube feeding peristaltic pump 42.

Peristaltic pump 42 includes a pump input port 47 coupled to reservoir output port 45 and a pump output port 49 coupled to input port 36 of recirculating fluid tube 34. A pump output temperature sensor 86 and a pump safety shutoff temperature sensor 88 both are coupled between pump port 49 and recirculating fluid input port 36 of bandage assembly 12.

Pump output temperature sensor 86 provides a feedback to control system 44 for closed loop control of heater 40 to control fluid input temperature to tube 34 in bandage assembly 12 to a desired temperature, illustratively 37° Celsius. Safety shutoff temperature sensor 88 is similarly provided as a feedback to control system 44 and is used to disable and alarm apparatus 10 if recirculating fluid temperature exceeds a safe limit, such as 41° Celsius. Sensors 86, 88 illustratively are

non-contact, infrared sensors such as an IRt/c.01HB-J-37C sensor from Exergen Corp., although it is understood that other suitable sensors can be used.

Optionally, proximity sensors (not shown) can be used to ensure that temperature sensors 86, 88 are properly coupled. For example, temperature sensors 86, 88 and respective proximity sensors can be coupled to a housing or channel into which a tube from recirculating fluid supply input port 36 is installed. If the proximity sensors do not detect the tube's presence within the channel, control system 44 can react accordingly, such as by providing a suitable display and/or alarm and/or by shutting down the system.

Temperature control system 17 further includes a liquid leak sensor 90 coupled adjacent pump 42 to monitor leaks from pump 42 or adjacent tubing. Sensor 90 is illustratively a capacitive sensor pad located under peristaltic pump 42. Sensor 90 provides a signal to electronic control system 44, which can alarm and disable wound treatment apparatus 10 if a leak is detected.

Wound treatment apparatus 10 further includes a wound effluent drainage receptacle or bag 92 that collects fluid flowing from bandage assembly 12 out of drainage tube 24, including both fluid supplied into bandage assembly 12 from supply tube 22 and discharge from wound 16. Drainage bag 92 includes a vapor filter 94 to filter gaseous components of fluid exiting bandage assembly 12. Vapor filter 94 is illustratively a standard hospital ventilator exhaust filter configured to plug directly into the side of drainage bag 92.

An alternative embodiment wound treatment apparatus 10' is shown in Fig. 3. Apparatus 10' replaces wound effluent drainage bag 92 and vapor filter 94 of apparatus 10 with a liquid trap bottle 96, a vacuum pump 98, and a vacuum filter 100 coupled between trap bottle 96 and pump 98. Liquid trap bottle 96 is coupled to drainage tube 24 to collect liquids in the fluid flow from bandage assembly 12. Vacuum pump 98 is used to apply a negative pressure to facilitate drainage. If desired, sufficient negative pressure can be applied so that negative pressure on the wound facilitates its closure. Filter 100 illustratively is a hydrophobic bacteria filter coupled between trap bottle 96 and vacuum pump 98.

Referring now to Figs. 4-10, bandage assembly 12 includes delivery bandage 18 and drainage bandage 20. Delivery bandage 18 includes bottom and top

sheets 102, 104 that sandwich both medicinal fluid supply tube 22 and recirculating fluid tube 34. Drainage bandage 20 includes bottom and top sheets 106, 108 that sandwich an adsorbent pad 110 and drainage tube 24. Adsorbent pad 110 is illustratively formed from medical grade hydrophilic foam, although any suitable material such as an absorbent substance can be used. Bandage sheets 102, 104, 106, 108 are illustratively formed from clear, flexible polyurethane or vinyl that meets USP Class VI requirements for medical applications.

Delivery bandage bottom sheet 102 is formed with a generally square perimeter 112 having rounded corners 114 and a tab 116 along a side of perimeter 112 as best shown in Fig. 5. Bottom sheet 102 further includes a central wound drainage passageway 118, a plurality of medicinal fluid supply passageways 120 arranged in a circular pattern concentric with passageway 118, and a plurality of outer wound drainage passageways 122 arranged in another concentric circular pattern radially outward of delivery passageways 120. Delivery passageways 120 provide for delivery of fluid medications from medicinal fluid supply tube 22 to wound 16 and illustratively are relatively smaller than drainage passageways 118, 122 that provide for passage of wound drainage through delivery bandage 18.

Delivery bandage top sheet 104 is formed to include a perimeter 124, tab 126, central passageway 128, and outer passageways 130 that are configured to align with perimeter 112, tab 116, central passageway 128, and outer passageways 122 of bottom sheet 102 as best shown in Fig. 6. When top and bottom sheets 102, 104 are aligned, central passageways 118, 128 and outer passageways 122, 130 are in fluid communication and allow wound effluent to pass through bandage 18.

Medicinal fluid supply tube 22 and recirculating fluid tube 34 illustratively are contained within a multi-lumen tube 132 as best shown in Figs. 7 and 8. It is understood that separate tubes can be used. Multi-lumen tube 132 is a 65 durometer USP Class VI polyvinyl chloride triple lumen tube and has three channels, one of which defines supply tube 22 and the other two define portions of recirculating fluid tube 34. Tube 132 includes a terminal end 134 that defines an end of medicinal fluid supply tube 22.

Recirculating fluid tube 34 further includes a straight segment 136 that extends axially outward from end 134 and a generally circular segment 138 coupled to

straight segment 136 as best shown in Fig. 7. The geometry of recirculating fluid tube 34 can vary as needed to distribute temperature controlled fluid throughout delivery bandage 18. Temperature regulated fluid, illustratively water, is circulated through delivery bandage 18 in segments 136, 138 from temperature control system 17 to maintain bandage 18 at an optimal temperature for wound treatment. It is understood that the temperature of bandage 18 can be regulated by control system 44 according to a desired treatment protocol, for example by maintaining a temperature to maximize treatment effectiveness of an enzyme or other medicinal fluid supplied through medicinal fluid supply tube 22.

Delivery bandage 18 is formed by sandwiching multi-lumen tube 132 between top and bottom sheets 102, 104 so that tube 132 extends over tabs 116, 126 and circular segment 138 is concentric with central passageways 118, 128 as best shown in Fig. 10. Top and bottom sheets 102, 104 are bonded together by radio frequency (RF) welding. Circular RF welds 140, 142 seal the perimeter around each pair of aligned wound drainage passageways 118, 128, and 122, 130. A perimeter RF weld 144 seals the aligned perimeters 112, 124.

A fluid delivery chamber weld 146 extends from perimeter weld 144 and encompasses inner wound drainage passageway weld 140 to define a fluid delivery chamber 148 that is in fluid communication with delivery passageways 120 in bottom sheet 102 and terminal end 134 of medicinal fluid supply tube 22. Thus, aerosol or liquid medications supplied through medicinal fluid supply tube 22 from nebulizer 26 or medicinal pump 39 can be delivered through delivery bandage 18 to wound 16 through chamber 148 that is isolated from wound drainage passageways 118, 122, 128, 130. Recirculating fluid tube 34 illustratively is contained within delivery chamber 148, although it is understood that tube 34 could be isolated from chamber 148.

Delivery bandage 18 further includes a sealing gasket 150 coupled to bottom sheet 102 adjacent its perimeter 112 as shown in Figs. 4 and 9. Gasket 150 is illustratively a thin foam frame that includes an adhesive coating for coupling gasket 150 both to bottom sheet 102 and for removably coupling gasket 150 to a patient's skin 14. Gasket 150 provides an improved seal between bottom sheet 102 of delivery bandage 18 and skin 14 to allow wound treatment apparatus 10 to control the topical

atmosphere adjacent wound 16. It is understood that other suitable materials can be used to provide a gasket, such as an appropriate layer of adhesive material.

Bottom sheet 106 of drainage bandage 20 includes a perimeter 152, central drainage passageway 154, and outer drainage passageways 156 that are configured to align with the corresponding perimeter 124 and passageways 128, 130 of top sheet 104 of delivery bandage 18. Bottom sheet 106 includes a thin layer of adhesive 158 formed as an open frame adjacent perimeter 152 to provide for removably coupling to delivery bandage top sheet 104. Adhesive 158 is configured to remain on bottom sheet 106 of drainage bandage 20 after uncoupling to allow for easy replacement of drainage bandage 20 without the need to remove delivery bandage 18.

Top sheet 108 of drainage bandage 20 has no passageways and is configured to align with bottom sheet 106 to provide a cavity 160 that receives adsorbent pad 110. Drainage bandage 20 is formed by sandwiching drainage tube 24 between top and bottom sheets 106, 108, which are then sealed together by RF welding adjacent their perimeters. Drainage bandage 20 thus channels wound effluent from delivery bandage 18, through pad 110, and out drainage tube 24 in an assembly that is easily replaceable, for example when adsorbent pad 110 becomes saturated or otherwise contaminated.

Bandage assembly 12 thus provides a two-piece bandage in which drainage bandage 20 can be removed and replaced while leaving delivery bandage 18 in situ. Drainage passageways 118, 122, 128, 130 thus allow for access to wound 16 through delivery bandage 18 when drainage bandage 20 is removed. Thus, a medical care giver can take a culture or sample from wound 16 without the need to remove delivery bandage 18.

An alternative embodiment bandage assembly 12' includes a one-piece combination delivery and drainage bandage comprising a delivery bandage portion 18' and drainage bandage portion 20' as shown in Fig. 11. Delivery bandage portion 18' includes a bottom sheet 102' that has a single drainage passageway 118' and a plurality of medicinal fluid delivery passageways 120'. Top sheet 104' includes a single drainage passageway 128'. Delivery bandage portion 18' includes a medicinal fluid supply tube 22' for use as discussed above in providing nebulized or liquid medication, etc. Drainage bandage portion 20' includes a pad 110', a top sheet 108', and a drainage tube

24'. Drainage tube 24' is coupled to bandage assembly 12' between sheets 104' and 108'.

Another alternative bandage assembly 12" is formed with only top and bottom sheets 102", 104" as shown in Fig. 12. Bottom sheet 102" includes a central drainage passageway 118" and a plurality of delivery passageways 120" arranged in a circular pattern radially outward of drainage passageway 118". A medicinal fluid supply tube 22" and a drainage tube 24" are coupled between top and bottom sheets 102", 104", with radio frequency welds (not shown) isolating the delivery tube and passageways 22", 120" from drainage tube 22" and passageway 118".

Yet another alternative bandage assembly 12"' is formed with elongated top and bottom sheets 102"', 104"' as shown in Fig. 13. Delivery passageways 118"' are arranged in a rectangular pattern to provide for delivery of fluid medication and control of the topical atmosphere adjacent a surface wound 16 having an elongated shape. Drainage passageway 120"' is illustratively circular, although drainage passageway 120"' can be formed in any suitable shape, such as an elongated rectangular or elliptical opening. Embodiment 12"' illustrates how bandages according to the present invention can readily be adapted for treatment of any wound shape by suitable geometric adaptations of the bandage assembly.

Another alternative drainage bandage 20" includes a bottom sheet 106", a top sheet 108", and a pad 110" as shown in Fig. 14. Bottom and top sheets 106", 108" are formed with respective passageway portions 107", 109". Bandage 20" is formed by welding sheets 106", 108" together at their perimeters so that passageway portions 107", 109" form a passageway suitable for coupling to a drainage tube 24. Bandage 20" can be used as discussed above for bandage 20 so that wound effluent from a delivery bandage travels through drainage bandage 20" as shown by arrows 99", 101".

As mentioned above, heater 40 can be replaced by other heating systems, such as recirculating fluid heating assembly 200 as shown in Figs. 15-18. Fig. 15 also shows yet still another alternative embodiment bandage assembly 12"". Bandage assembly 12"" includes a delivery bandage portion 18"" that differs from delivery bandage 18 as shown in Figs. 4-6 essentially in its outer wound drainage passageways 122"", which are formed as truncated arc segments. Bandage assembly

12"" includes a drainage bandage portion 20"" essentially the same as drainage bandage 20" discussed just above. Bandage assembly 12"" further includes a drainage tube 24 coupled to a wound drainage vapor filter 94.

Heating assembly 200 includes a radiant heating plate 202 configured to be coupled with a recirculating fluid path assembly 204 that transports recirculating fluid in a circuitous path past plate 202. As shown in Fig. 15, fluid path assembly 204 includes a tube section 206 configured to be laced into a channel 208 in a peristaltic pump 42 that pumps the recirculating fluid through assembly 200. Fluid path assembly 204 further includes input and output ports 210, 212 that are coupled to a nebulizer cap 214, which in turn is coupled both to a nebulizer 26 and to a multi-lumen tube 132 leading to bandage assembly 12"". Tube 132 is coupled to bandage assembly 12"" by a connector 216.

Fluid path assembly 204 is illustratively formed by welding two flexible plastic sheets together to form a circuitous fluid input pathway 218 and a circuitous fluid output pathway 220 as shown in Fig. 16. Input pathway 218 is coupled to input port 210 and tube section 206; output pathway 220 is coupled to tube section 206 and output port 212. Fluid path assembly 204 is folded along its centerline 222 as shown in Fig. 17 so that input pathway 218 is opposite output pathway 220. Side edges 224, 226 that extend from centerline 222 are then welded together as shown by arrows 230 to create a pocket 228 configured to receive heating plate 202 so that recirculating fluid travels circuitously through fluid path assembly 204 past heating plate 202.

As fluid flows through fluid path assembly 204 past heating plate 202, fluid temperature is measured, for example, by infrared heat sensors 238. Recirculating fluid temperature is then regulated to a desired value by controlling the heat output of plate 202 selectively based on measured fluid temperature. It is understood that fluid path assembly 204 can be replaced by any suitable mechanism, such as a tube coupled to flexible sheets, or by forming narrow pathways or parallel pathways within flexible sheets, etc. Essentially, the requirement is to provide recirculating fluid pathways capable of receiving heat from plate 202 in order to regulate the temperature of fluid flowing through the pathways.

Heating plate 202 is illustratively formed from two plate sections 228, 230 that are coupled to a base 232 as shown in Fig. 18. Plate sections 228, 230

include resistive heating elements 234 that are selectively controllable to heat recirculating fluid as it flows in fluid path assembly 204 past plate 202. Plate sections 228, 230 further include holes 236 to facilitate use of infrared temperature sensors for measuring recirculating fluid temperature. Plate 202 and sensors 238 are coupled to control system 44 to provide for automated temperature control of recirculating fluid.

An alternative drainage system 162 as shown in Fig. 19 can be used in the wound treatment apparatus 10, 10' of Figs. 2 and 3 to provide for automated monitoring and switching of drainage bags by control system 44. Drainage system 162 includes first and second drainage bags 164, 166, and valves 168, 170 that are coupled between drainage bags 164, 166 and wound drainage tube 24. Drainage bags 164, 166 include pressure sensors 172, 174 that provide signals to control system 44 indicative of bag pressure, which correlates to whether the bag is full and needs to be changed. Bags 164, 166 further include bacteria filters 190, 192 and exhaust valves 186, 188 that control system 44 can use to vent excess pressure from within bags 164, 166.

Drainage bags 164, 166 are coupled to a pump 176 through valves 178, 180, pressure regulator 182, and filter 184. Valves 168, 170 are coupled to control system 44 to allow for automated selection of which drainage bag will receive effluent from bandage assembly 12, 12'. Drainage system 162 thus allows for automated and continuous operation of wound apparatus 10, 10'. In operation, valve 170 is closed and valve 168 is opened to permit filling of bag 164. When sensor 172 indicates to control system 44 that bag 164 is full, valve 168 is closed and valve 170 is opened to permit filling of bag 166. With valve 168 closed, valve 178 opens to supply pressure to bag 164 to force the contents of bag 164 out through bacteria filter 190. When sensor 174 detects that bag 166 is full, valve 170 is closed and valve 168 is opened to permit filling of bag 164 again. With valve 170 closed, valve 180 opens to supply pressure to bag 166 to force the contents of bag 166 out through bacteria filter 192. This cycle repeats itself so that tube 24 is not exposed to back pressure.

Referring now to Figs. 20 and 21, an additional embodiment of wound treatment apparatus 320 comprises a medicinal fluid supply 322 to deliver fluid to wound 16, and a vacuum 326 and waste receptacle 324 to draw and store the fluid from wound 16. A supply tube 328 is connected to fluid supply 322 and to a fluid junction array 330. Fluid junction array 330 includes a fluid delivery conduit or

deposit membrane 332 having an opening 333, and a circulating tube coupler 334. Opening 333 is positioned near wound 16. Illustratively, deposit membrane 332 can be made from two sheets laterally sealed on each side or it can be made from a simple tube. The material used to make membrane 332 can be rubber, plastic or any other suitable material. In addition, in one illustrative embodiment, membrane 332 has a flare 338 leading to opening 333, as best shown in Fig. 21. Flare 338 allows selective control over the flow rate of the medicinal fluid. The operator may cut membrane 332 thereby reducing its length, and increasing the flow of the medicine. The more flare 338 that is cut off, the faster the flow rate.

Circulating tube coupler 334 illustratively comprises dual ends 340 and 342, respectively. Each end illustratively 340 and 342 extend from opposite sides of membrane 332. (See Fig. 21.) Circulating tube 344 is connected to each end 340 and 342 encircling the periphery of wound 16 on healthy tissue. Fluid collection openings or notches 346 are formed intermittently along the length of tube 344. Illustratively, end 342 is connected to outlet tube 348 whereas end 340 is a terminated end. This forces all of the fluid in tube 344 to travel in one direction toward outlet tube 348. As a result, fluid flows out from membrane 332 passing over wound 16, drawing through notches 346 into tube 344, and exiting through outlet tube 348. Vacuum 326 communicates with outlet tube 348 via vacuum tube 350 and waste receptacle 324 to assist in drawing fluid from wound 16 into waste receptacle 324.

Circulating tube 344 may include a bendable wire 352 extending therethrough. Bendable wire 352 provides a semi-ridged form for tube 344 so that it may be selectively positioned about the periphery of wound 16 and hold its shape. As shown in Fig. 22, diameter 358 of bendable wire 352 is less than inner diameter 354 of circulating tube 344, thereby not inhibiting the flow of fluid.

Fluid junction array 330 attaches to adhesive 361 which adheres to a portion of healthy tissue surrounding wound 16. It is appreciated, however, that array 330 may be attached to the skin by any variety of suitable means. Top sheet 362 is sized to cover apparatus 320 and may be removably attached directly to healthy skin (not shown). Top sheet 362 is illustratively formed from a clear, flexible polyurethane or vinyl that meets USP Class VI requirements for medical applications. Gasket or order 360 is illustratively formed with a generally square perimeter having

rounded corners attaching to the skin about the periphery of tube 344 and serves as a seal. In one embodiment, border 360 is positioned underneath top sheet 362, as shown in Fig. 21. In addition, border 360 attaches to array 330 by a pair of fasteners 364 that extend through apertures 366.

Another embodiment of the wound treatment apparatus is indicated by reference number 368 and is shown in Figs. 23 and 24. A fluid supply tube 382 leads illustratively into outer chamber 378. Outer chamber 378 is formed about the periphery of inner chamber 374. Chambers 374 and 378 are formed by a top sheet and a bottom sheet 372 and 373, respectively. (See Fig. 24.) Illustratively, RF welds about the periphery of inner chamber 374 and about the periphery of outer chamber 378 further defines the chambers within sheets 272 and 273. The welds form an inner border and an outer border 375 and 380, respectively. It is understood that any suitable means can be used to form borders 375 and 380, in place of ultra-sonic welds. For example, borders 375 and 380 can be made from adhesive or from heat selectively applied to sheets 372 and 373.

A gasket 383 is attached about outer border 380 of the bandage. Gasket 383 suspends sheets 372 and 373 forming a wound cavity 379 as shown in Fig. 24. An adhesive 384 is attached to the underside of gasket 383 to adhere to healthy skin tissue surrounding the wound (not shown) thereby holding apparatus 368 in place and containing the medicinal fluid in wound cavity 379.

Illustratively, medicinal fluid is deposited through tube 382 into outer chamber 378. Several passageways 377 are disposed, in spaced relation to each other, through lower sheet 373 into wound cavity 379. Medicinal fluid can then flow through passageways 377 into wound cavity 379 and onto the wound. The fluid is then drawn from the surface of the wound up through outlet aperture 376. Outlet aperture 376 is disposed through lower sheet 373 into inner chamber 374. With the assistance of a vacuum connected to outlet tube 370, the medicinal fluid is drawn from inner chamber 374 into tube 370 and ultimately into a waste receptacle. Fluid collection openings or notches 346 are formed intermittently along the length of tube 370 within inner chamber 374 to further assist in collecting fluid.

It is appreciated that the flow direction of the medicinal fluid may be reversed from that previously described. Illustratively, medicinal fluid can enter

apparatus 368 through outlet tube 370, and dispense through aperture 376 into wound cavity 379. Fluid can then be drawn through apertures 377 into outer chamber 378 and out through tube 382. Apertures 377 may be of any size suitable to draw the fluid from wound cavity 379 into chamber 378.

A still further embodiment of the wound treatment apparatus is indicated by reference number 386 and is shown in Figs. 25 and 26. In contrast to the previous embodiment, fluid supply tube 382 leads illustratively into inner chamber 374. Like the previous embodiment, outer chamber 378 is formed about the periphery of inner chamber 374. In addition, chambers 374 and 378 are formed by a top sheet and a bottom sheet 372 and 373, respectively. (See Fig. 26.) Again, illustratively, an RF weld about the periphery of inner chamber 374 and at the periphery outer chamber 378 further defines the chambers within sheets 372 and 373. The welds form an inner border and an outer border 375 and 380, respectively. It is understood that any suitable means can be used to form borders 375 and 380, in place of RF welds.

Illustratively, medicinal fluid is deposited through tube 382 into inner chamber 374. This is in contrast to the previous embodiment where tube 382 deposited fluid into outer chamber 378. Medicinal fluid can then flow through inlet aperture 385 that is disposed through bottom sheet 373 into wound cavity 379 and onto the wound. Several passageways 381 are disposed, in spaced relation to each other, through lower sheet 373 into wound cavity 379. In one illustrative embodiment, passageways 381 are larger in size than passageways 377 in the previous embodiment. The fluid is drawn from the surface of the wound up through passageways 381. In one embodiment, openings or notches 346 are formed intermittently along the portion of tube 391 extended within outer chamber 378. Tube 391 illustratively extends through outer chamber 380. With the assistance of a vacuum connected to outlet tube 391, the medicinal fluid is drawn up from outer chamber 378 into tube 391 and ultimately into a waste receptacle. Other features like gasket 383 and adhesive 384 are configured similar to that of the previous embodiment.

It is appreciated that the flow direction of the medicinal fluid may be reversed from that previously described. Illustratively, medicinal fluid can enter apparatus 386 through tube 391, flow out notches 388 and dispense through apertures 381 into wound cavity 379. Fluid can then be drawn through aperture 385 into inner

chamber 374 and out through tube 382. Apertures 381 may be of any size suitable to dispense the fluid from outer chamber 378 into wound cavity 379.

An additional embodiment of a wound treatment apparatus is indicated by reference number 392 and is shown in Figs. 27-29. Wound apparatus 392 comprises a fluid supply tube 396 extending illustratively near the center of apparatus 392 into a dispensing aperture 398. Aperture 398 opens to a wound cavity 400 formed on the underside of apparatus 392. (See Figs. 28 and 29.) Above wound cavity 400 and formed about dispensing aperture 398 is basin 402. Basin 402 is defined by inner and outer walls 410 and 412, respectively. Inner wall 410 separates the basin 402 from dispensing aperture 398. Outer wall 412 illustratively defines the periphery of basin 402. Columns 404 extend from basin 402, illustratively in a circular formation about inner wall 410, as shown in Fig. 27. A top sheet 405 is formed over basin 402, attaching illustratively to the top of outer wall 412. Columns 404 support top sheet 405 over basin 402. Top sheet 405 is thereby prevented from collapsing in on basin 404 and covering passageways 406 as a negative pressure is applied to bandage 392.

An adhesive 394 is attached to apparatus 392 illustratively about the periphery of cavity 400. As with previous embodiments, adhesive 394 adheres to healthy skin tissue surrounding the wound. It is appreciated that adhesive 394 may be replaced with any variety of means to secure wound apparatus 392 over the wound.

Illustratively, medicinal fluid flows from tube 396 through aperture 398 into wound cavity 400 and onto the wound. The fluid then draws up through passageways 406 collecting in basin 402. The collected fluid is then drawn from basin 402 into outlet tube 414 and ultimately into a waste receptacle (not shown). As with other embodiments previously discussed, a vacuum may illustratively be attached to outlet tube 414 in the manner previously described.

It is appreciated, however, that the flow direction of the medicinal fluid in apparatus 392 may be reversed from that previously described. Illustratively, medicinal fluid can enter through tube 414, flow into wound cavity 400 through passageways 406. The fluid can then be drawn through aperture 398 into tube 396. Apertures 406 may be of any size suitable to dispense or draw the fluid to or from wound cavity 400.

Another embodiment of the present invention includes a flexible wound treatment apparatus 420 shown in Figs. 30-32. An inlet tube 382 is extended through top panel 422 into chamber 424. Chamber 424 is formed between top panel 422, mid-panel 426, and is defined by inner and outer borders 375 and 380, respectively. (See Figs. 30 and 31.) Illustratively, an RF weld about the peripheries of chamber 424 forms borders 375 and 380 as previously discussed. Several apertures 377 are disposed through mid-panel 426 into an expanded wound cavity 428. Wound cavity 428 is defined by two laterally space side walls 430 and 432 and two end walls 434 and 436 extending between said side walls 430 and 432. Mid-panel 426 interconnects to the coplanar edges of walls 430, 432, 434, and 436. The resultant form is a flexible bellow or flexible body. A spacer 442 is fitted within the periphery of wound cavity 440. Spacer 442 is illustratively made from a foam material but it is understood that it can be made from any suitable material that will assist in maintaining the form of the expanded wound cavity 428 as shown in Figs. 31 and 32.

Formed about the periphery of wound cavity 428 and attached to coplanar edges of said walls 430, 432, 434, and 436 opposite mid panel 426, is a pad 438. Pad 438 is illustratively made from a thin flexible foam material and often with a plastic-like top coating. Pad 438 provides a cushioning intermediary between the walls 430, 432, 434, and 436, and an adhesive 440. Adhesive 440, is a similar panel to those adhesives described in the previous embodiments.

Flexible wound treatment apparatus 420 is optimum for use on flexible joints like knees and elbows. This is because spacer 442 keeps mid-panel 426 raised enough so that as wound 16 is raised as the joint bends, wound 16 will not be interfered with by mid-panel 426. (See Fig. 32.)

Illustratively, and in similar fashion to previous embodiments, tube 382 deposits medicinal fluid into chamber 424 where it flows through passageways 377 into cavity 428. An outlet tube 448 is extended illustratively through top panel 422, over spacer 442, and into wound cavity 428. Notches 346 can be formed in the length of tube 448 positioned within cavity 428 so that after the fluid has deposited onto wound 16 it is drawn up through opening 437 and/or notch 346 into outlet tube 448. Like previous embodiments, it is understood that the flow of the medicinal fluid can be

reversed. The fluid can be deposited onto wound 16 by tube 448 and drawn up through passageways 377 into chamber 424 and out tube 382.

A further embodiment of the present invention comprises a heat and heat sensing system 500 (collectively, heat system 500) coupled, illustratively, with bandage 499 as shown in Fig. 33. It is appreciated that heat system 500 can be coupled with any bandage described herein. Heat system 500 includes a heating and sensing pad 502, thermocouples 508 and 510, a tube assembly 504, and a patch unit connector 506. Pad 502 is the portion of system 500 that transfers heat to bandage 499 as well as senses the amount of heat that was transferred. Illustratively, pad 502 includes a thermocouple 508 that supplies heat to pad 502, See Fig. 34. A second thermocouple 510 senses the heat that is being supplied by thermocouple 508. Pad 502 can be made, illustratively from silicone, but it is appreciated that pad 502 can be made from any suitable material serving the same function as silicone. Pad 502 can be either inserted into a pocket 503 within the bandage or coupled to the bandage by any suitable means. In addition, alternatives to pad 502 can be used to transfer heat from thermocouple 508 to bandage 499. Both thermocouples 508 and 510 extend from pad 502 to patch unit connector 506. Illustratively, the thermocouples can be contained in tube 504 protecting same. Tube 504 can be flexible and made from any suitable material, and be of any suitable length.

Patch connector 506 connects to a nebulizer cartridge (not shown) and can be removed for continual use on additional bandages. A double lumen tube 512 can connect to tube connector 513 to supply medicinal fluid to bandage 499 and draw fluid away from same, as hereinbefore described.

Although the invention has been described in detail with reference to certain preferred embodiments, variations and modifications exist within the scope and spirit of the present invention as described and defined in the following claims.

CLAIMS:

1. A wound treatment apparatus comprising:

a bandage configured to cover a wound and provide a seal about the perimeter of the wound, the bandage providing a cavity over the wound, a fluid supply in communication with the cavity, and a fluid drainage in communication with the cavity.

2. The apparatus of claim 1, further comprising a nebulizer coupled to the fluid supply.

3. The apparatus of claim 1, further comprising a liquid medication pump coupled to the fluid supply.

4. The apparatus of claim 1, further comprising a vacuum pump coupled to the fluid drainage, said bandage providing a relatively closed space above the wound to be held at a negative pressure.

5. The apparatus of claim 1, further comprising a recirculating, temperature regulated fluid tube coupled to the bandage.

6. The apparatus of claim 5, further comprising a heater and a circuitous fluid pathway coupled to the recirculating, temperature regulated fluid tube.

7. The apparatus of claim 6, further comprising a temperature sensor coupled to the recirculating, temperature regulated fluid tube.

8. The apparatus of claim 7 further comprising a controller and a cut-off valve, the controller being coupled to the temperature sensor and the cut-off valve, the cut-off valve being coupled to the fluid supply tube, and the controller being configured to activate the cut-off valve based on a signal from the temperature sensor.

9. The apparatus of claim 3, further comprising an oxygen supply coupled to the fluid supply.

10. The apparatus of claim 9, further comprising an oxygen supply, an air supply, and a valve system, the valve system having a first input coupled to the oxygen supply, a second input port coupled to the air supply, and an output port coupled to the medicinal fluid supply device.

11. The apparatus of claim 10, wherein the valve system is a dual input selector valve.

12. The apparatus of claim 1, further comprising a pressure sensor coupled to the fluid supply tube.

13 The apparatus of claim 12, further comprising a pressure sensor coupled to the fluid supply tube, and a controller coupled to the pressure sensor and a display, the controller being configured to cause an indicia to appear on the display based on a value received by the controller from the pressure sensor.

14. The apparatus of claim 12, further comprising a controller coupled to the pressure sensor and configured to signal an alarm if a value received by the controller from the pressure sensor exceeds a predetermined threshold.

15. The apparatus of claim 1, further comprising a gasket configured to be coupled between the bandage and a skin surface about the wound.

16. The apparatus of claim 1, wherein the bandage comprises a two-piece bandage assembly including a supply bandage configured to seal the wound and provide the said cavity and a drainage bandage configured to be coupled to the supply bandage.

17. The apparatus of claim 1, wherein the bandage comprises a fluid delivery conduit, said conduit being configured to be positioned near a wound to deliver fluid to the wound, and a fluid drainage conduit having at least one fluid collection opening, the conduit being positioned about the wound.

18. The wound treatment apparatus of claim 16, wherein the fluid delivery conduit has a flare.

19. The wound treatment apparatus of claim 16, in which said bandage covers the fluid delivery and drainage conduits forming a closed space over and about the wound.

20. The apparatus of claim 2, further comprising a sensor coupled to the nebulizer and configured to provide a signal indicative of an amount of fluid within the nebulizer.

21. The apparatus of claim 12, wherein the sensor is an acoustic sensor.

22. The apparatus of claim 12, further comprising a controller coupled to the sensor and configured to determine if a nebulizer fluid reservoir contains a fluid based on values received by the controller from the sensor.

23. The apparatus of claim 2, further comprising an electronic control system coupled to the nebulizer to control nebulizer output.

24. A wound treatment apparatus comprising:

a first bandage configured to cover a wound, the first bandage including a first surface configured to face toward the wound, at least one fluid delivery passageway through the first surface, and at least one fluid drainage passageway through the first surface;

a fluid delivery conduit in communication with the fluid delivery passageway;

a second bandage configured to be coupled with the first bandage, the second bandage including a second surface configured to face toward the first bandage and provide a fluid space between the surfaces; and

a fluid drainage conduit in communication with the fluid drainage passageway.

25. The apparatus of claim 24, wherein the at least one delivery passageway comprises a plurality of delivery passageways.

26. The apparatus of claim 25, wherein the plurality of delivery passageways is arranged in a substantially circular pattern.

27. The apparatus of claim 24, further comprising a fluid drainage receptacle coupled to the fluid drainage tube.

28 The apparatus of claim 27, further comprising a filter coupled to the fluid drainage receptacle.

29. The apparatus of claim 24, wherein the first bandage comprises a first flexible relatively impermeable sheet including the first surface, and the second bandage comprises a second flexible relatively impermeable sheet including the second surface, said second bandage providing a close space over the wound to be held at a negative pressure.

30. The apparatus of claim 24, further comprising a gasket configured to be coupled between the bandage and a perimeter of healthy tissue surrounding the wound to provide a relatively closed space about the wound to be held at a negative pressure.

31. The apparatus of claim 24, wherein the fluid space is segregated into a first chamber and a second chamber, wherein the first chamber is formed about the fluid delivery passageway and the second chamber is formed about the fluid drainage passageway.

32. The apparatus of claim 31, wherein the fluid delivery conduit is in communication with the first chamber and the fluid drainage conduit is in communication with the second chamber.

33. A wound treatment apparatus comprising:

a bandage including a wound facing surface configured to face toward the wound and a fluid drainage passageway having an opening adjacent the wound facing surface;

a fluid drainage tube coupled to the fluid drainage passageway;

first and second fluid drainage receptacles coupled to the drainage tube; and

first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively.

34. The apparatus of claim 33, wherein the valves are pinch valves.

35. The apparatus of claim 33, further comprising a sensor coupled to the first fluid drainage receptacle to provide a signal indicative of an amount of fluid in the receptacle.

36. A wound treatment apparatus comprising:

a cover bandage configured to cover a wound and provide a seal on healthy skin tissue about the perimeter of the wound, said cover to provide a relatively closed space about the wound to be held at negative pressure;

a fluid supply conduit fitted between the cover bandage and healthy skin tissue near the wound; and

a fluid drainage conduit having at least one fluid drainage opening, fitted between the cover bandage and healthy skin tissue and positioned on healthy skin tissue about the wound and the fluid supply.

37. The apparatus of claim 36, further comprising a medicinal fluid supply in communication with the fluid supply conduit.

38. The apparatus of claim 36, further comprising a drainage receptacle in communication with the fluid supply conduit and a vacuum.

39. The apparatus of claim 36, wherein the fluid drainage conduit has a bendable wire extended through the length of the conduit.

40. A wound treatment apparatus comprising:

a cover bandage providing a closed seal about a wound and a relatively closed cavity over the wound to be held at a negative pressure, the cover bandage including a first surface configured to face toward the wound, at least one fluid delivery passageway through the first surface, and at least one fluid drainage passageway through the first surface, a second surface configured to face toward the first surface and provide a fluid space between the surfaces; the fluid space is segregated into a first chamber and a second chamber, wherein the first chamber is formed about the fluid delivery passageway and the second chamber is formed about the fluid drainage passageway;

a fluid delivery conduit in fluid communication with the first chamber and the fluid delivery passageway; and

a fluid drainage conduit having at least one fluid drainage opening, in fluid communication with the second chamber and the fluid drainage passageway.

41. The apparatus of claim 40, wherein the fluid drainage conduit is positioned within the first chamber.

42. A wound treatment apparatus comprising:

a cover bandage providing a closed seal about a wound positioned on a joint having a cavity over the wound sized to receive the joint and to be held at a negative pressure, the cover bandage including a first surface configured to face toward the wound, at least one fluid delivery passageway through the first surface, and a second surface configured to face toward the first surface providing a fluid space between the surfaces;

a fluid delivery conduit in fluid communication with the fluid space and the fluid delivery passageway; and

a fluid drainage conduit having at least one fluid drainage opening, in fluid communication with the cavity.

43. The apparatus of claim 42, further comprising a heater and heat sensor coupled to the cover bandage.

44. The apparatus of claim 43, further comprising a heater and heat sensor coupled to the cover bandage and to a nebulizer.

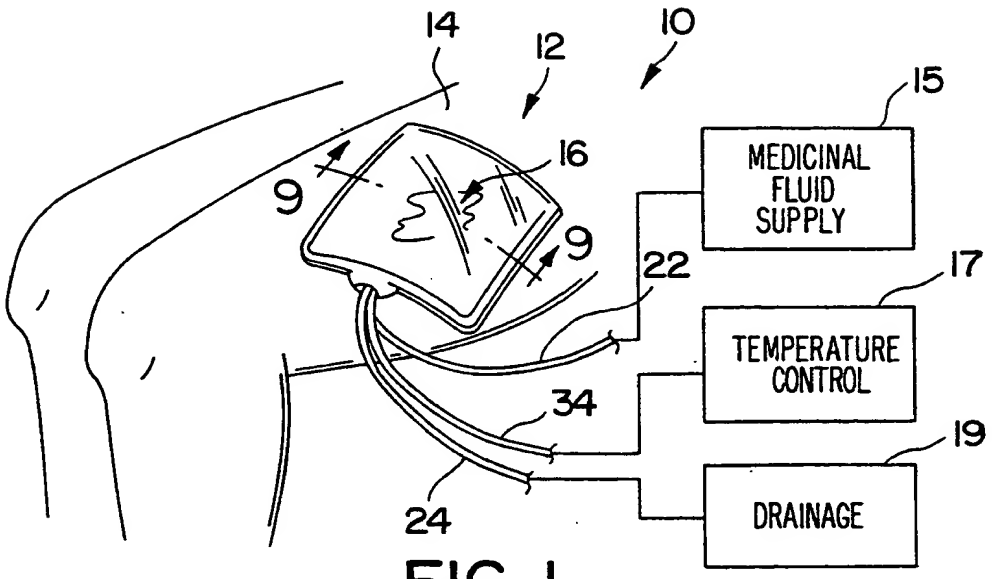

14
12
10
15
16
9
9
MEDICINAL FLUID SUPPLY
22
17
TEMPERATURE CONTROL
34
19
24
DRAINAGE

FIG. 1

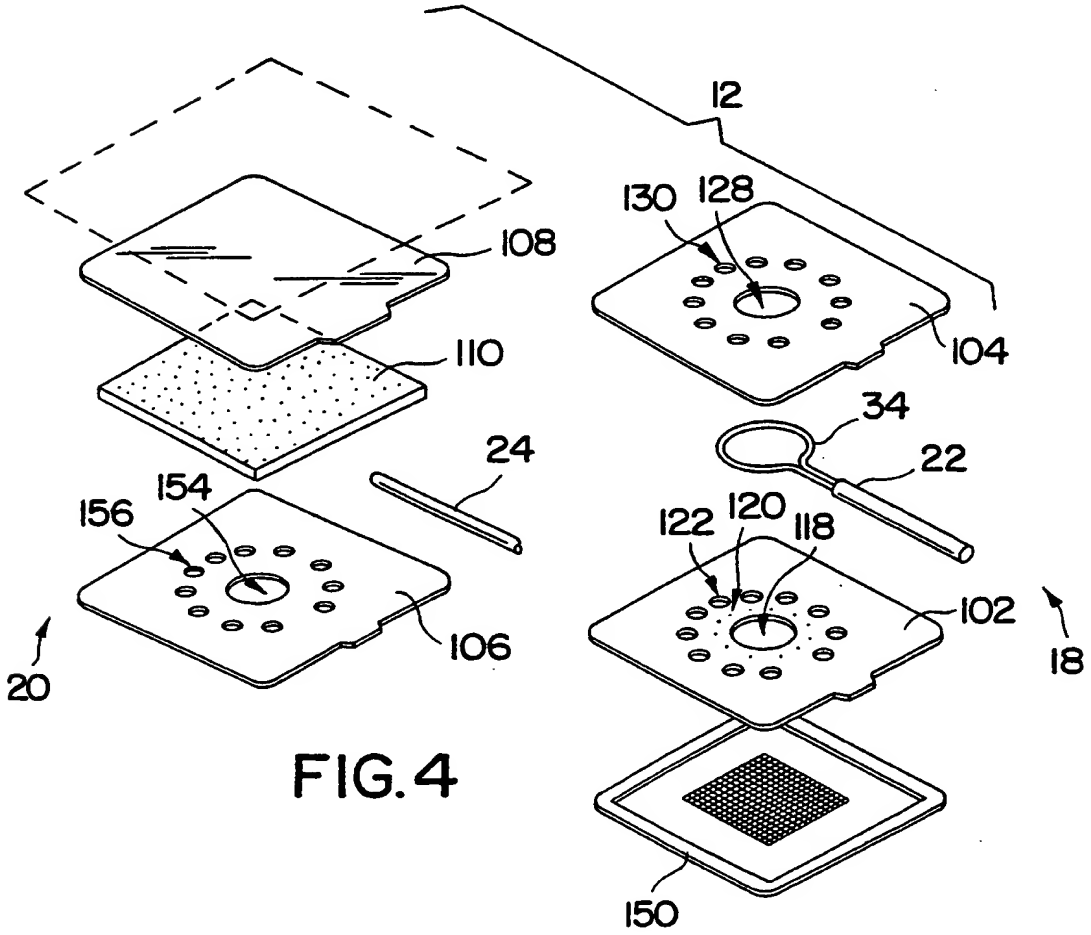

12
108
130
128
110
104
34
24
22
154
156
120
122
118
102
106
20
18
150

FIG. 4

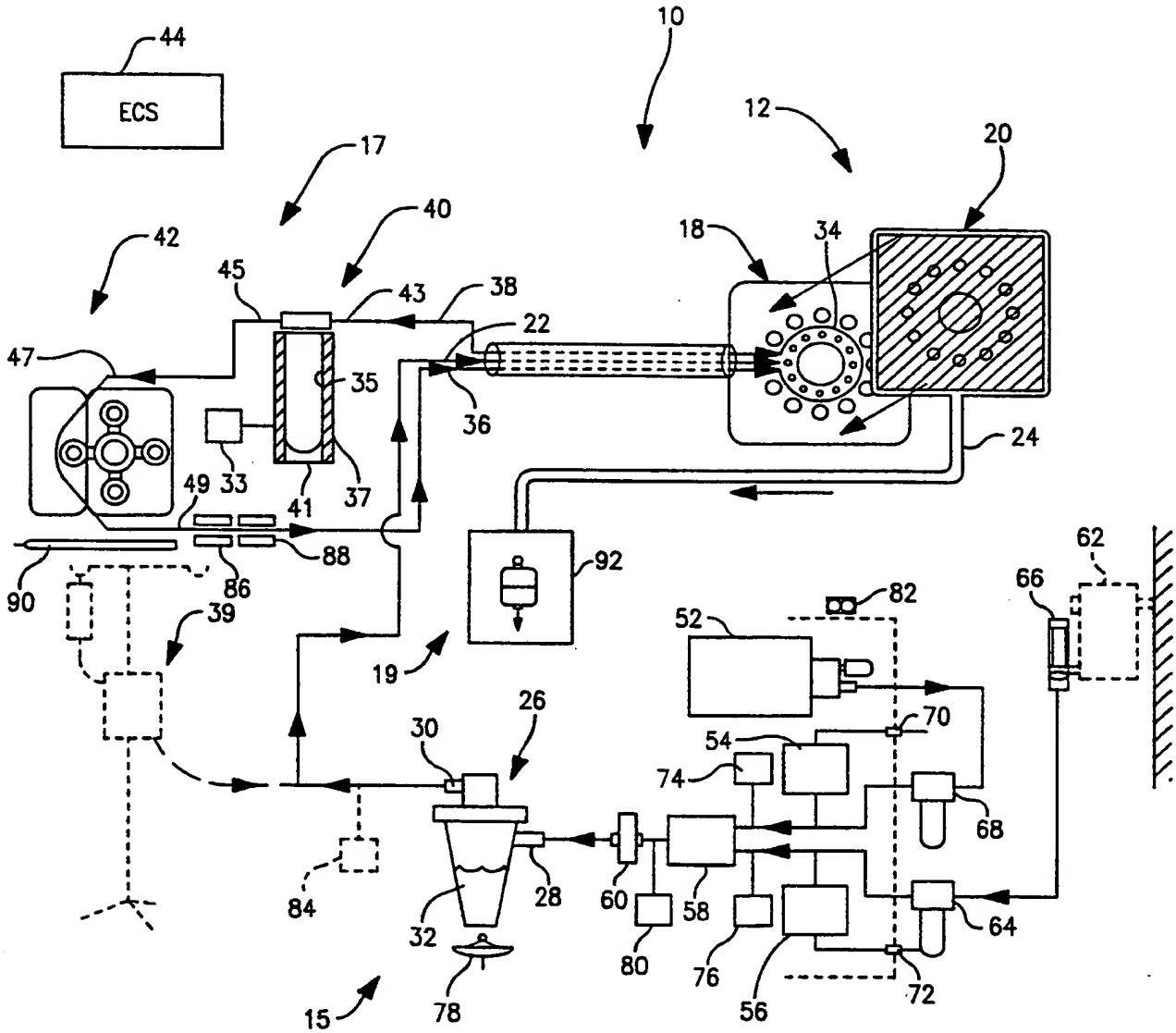

ECS
44
10
12
20
17
40
42
18
34
45
43
38
22
47
35
36
24
49
33
41
37
88
90
86
39
92
62
66
82
52
19
26
30
70
54
74
68
84
28
60
58
64
32
80
76
72
78
15
56

FIG. 2

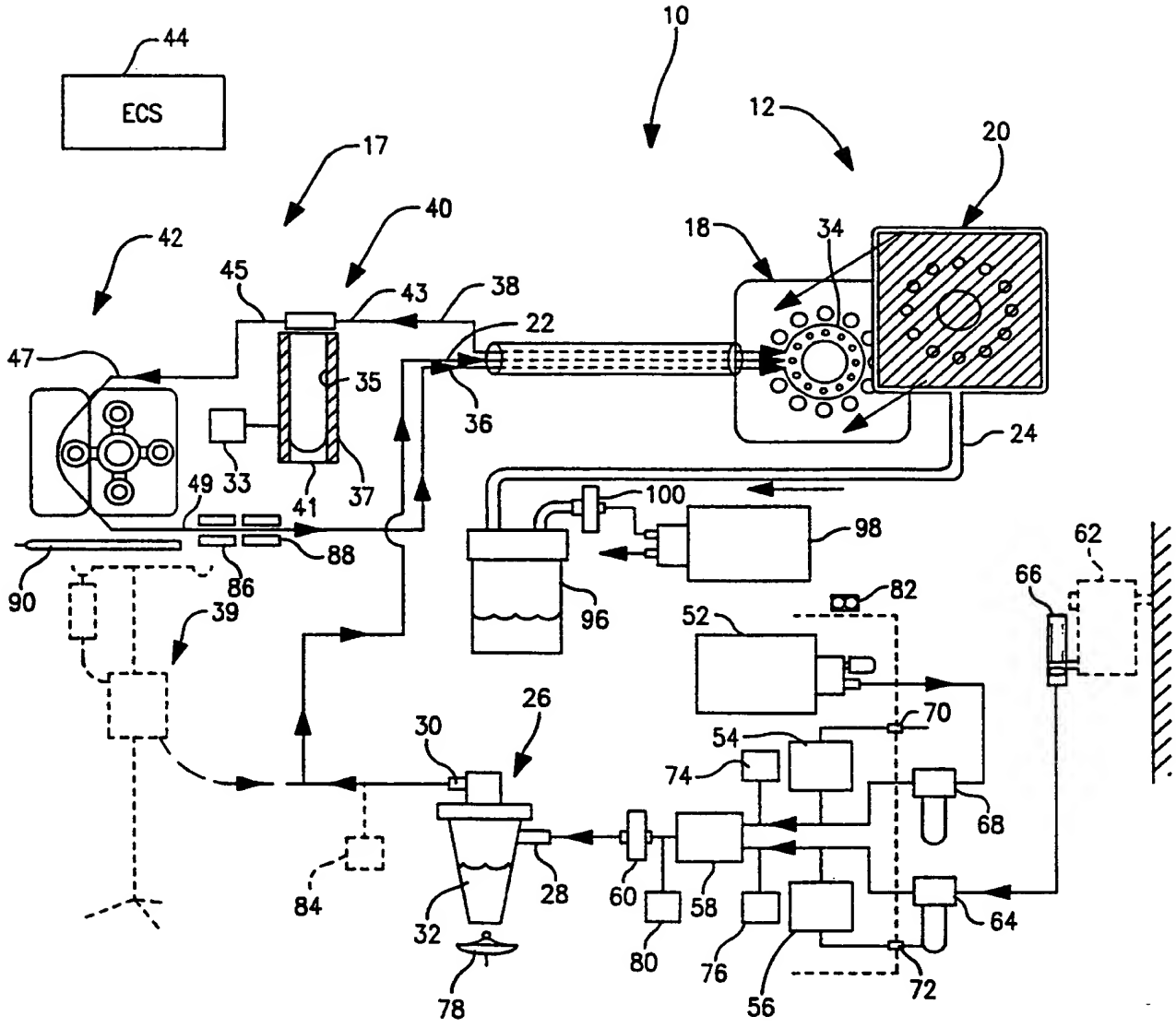

ECS
44
10
12
17
20
40
42
18
34
45
43
38
22
47
35
36
24
49
33
41
37
100
98
62
66
88
90
86
82
39
96
52
26
30
70
54
74
68
84
28
60
58
64
32
80
76
72
78
56

FIG. 3

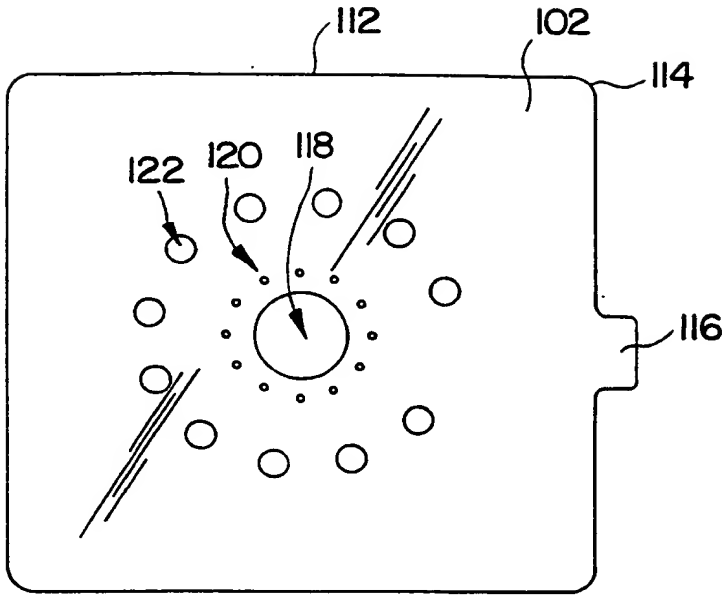


FIG. 5

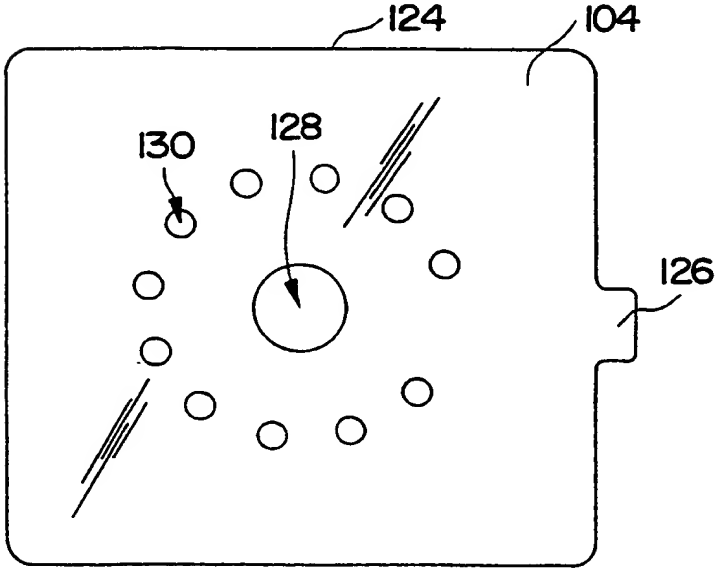


FIG. 6

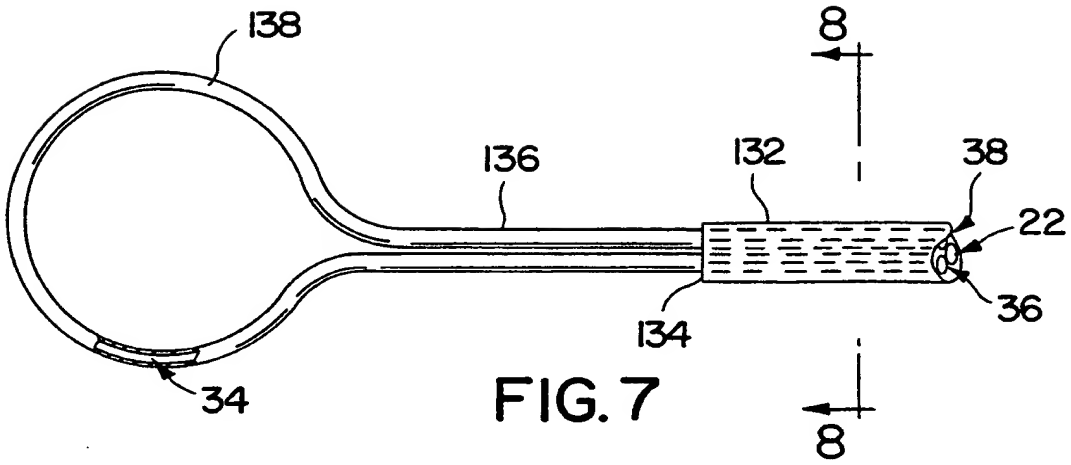


FIG. 7

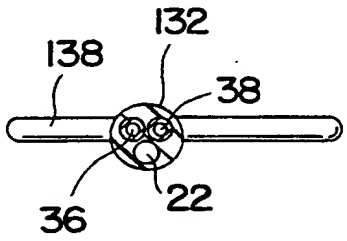


FIG. 8

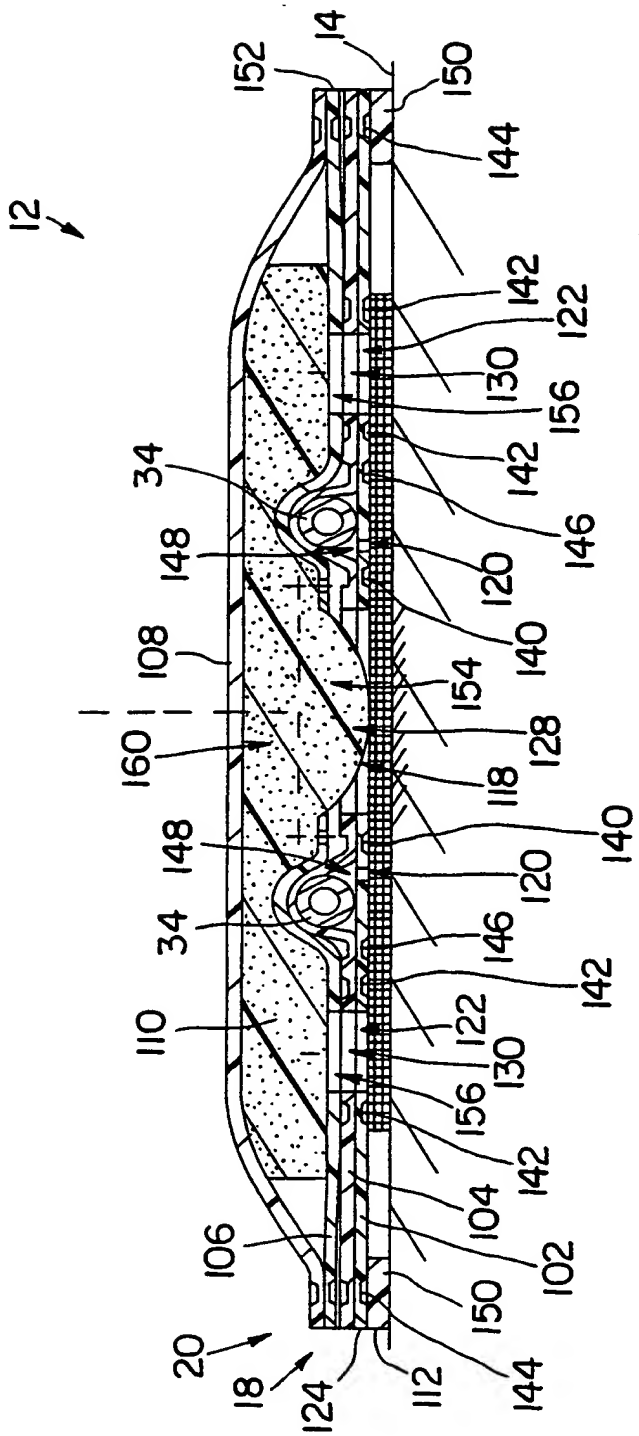

12
14
152
150
144
142
122
130
156
142
146
34
148
120
140
108
154
128
160
118
148
140
120
34
146
142
110
122
130
156
142
104
106
102
150
20
18
124
112
144

FIG. 9

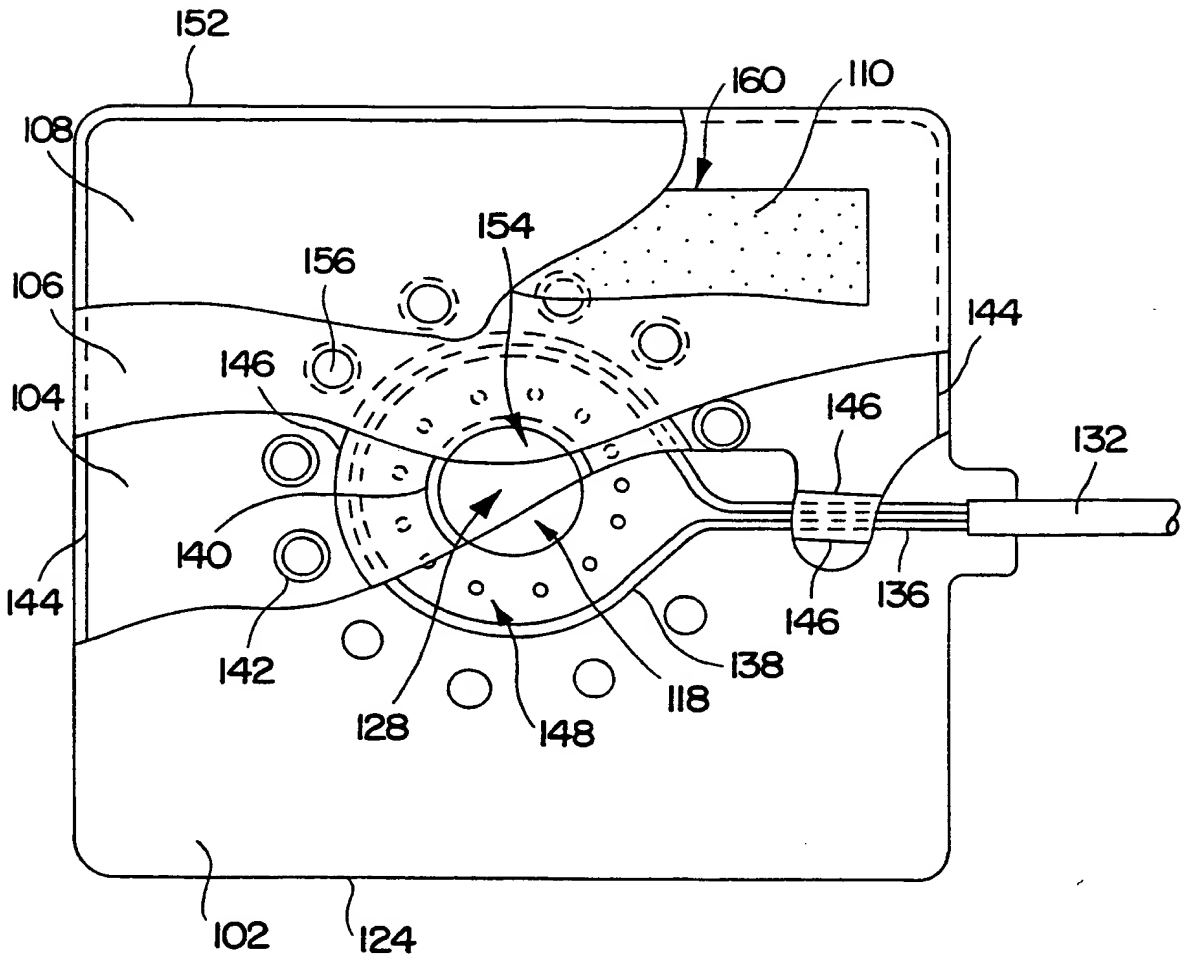

152
160
110
108
154
156
106
144
146
104
146
132
140
136
144
146
142
138
118
128
148
102
124

FIG. 10

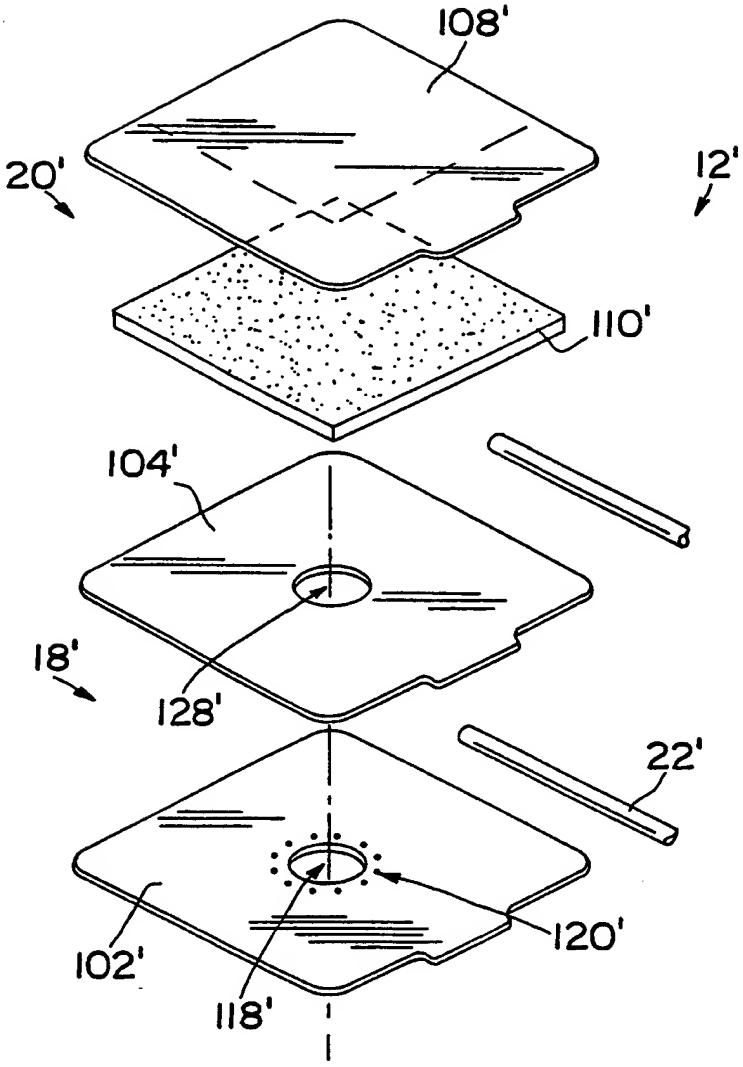


FIG. 11

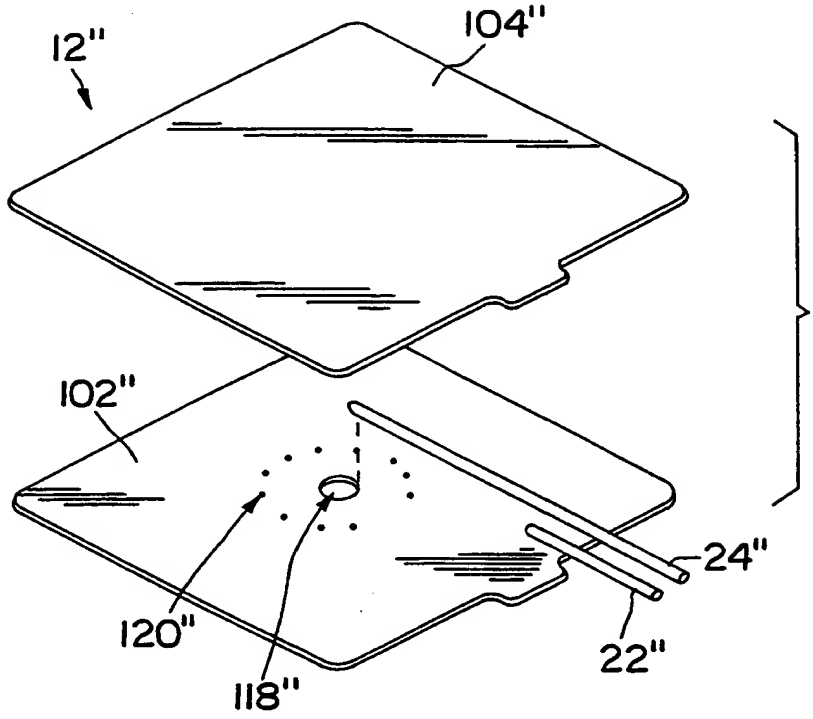


FIG. 12

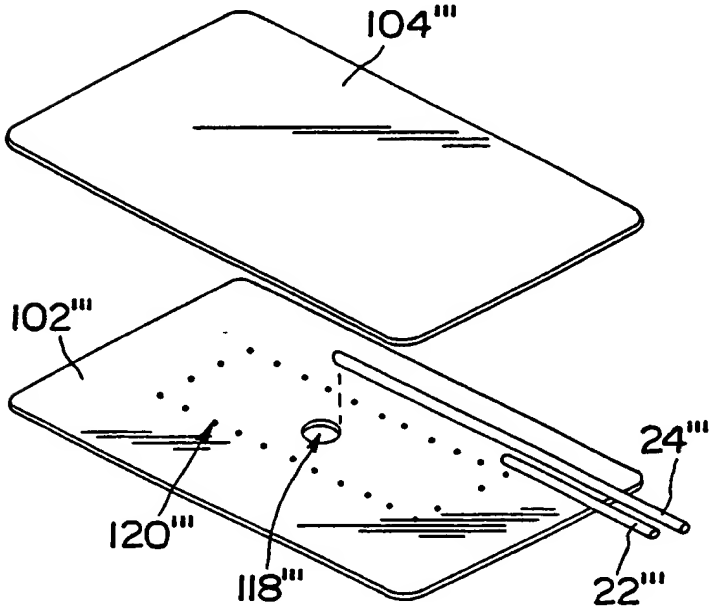


FIG. 13

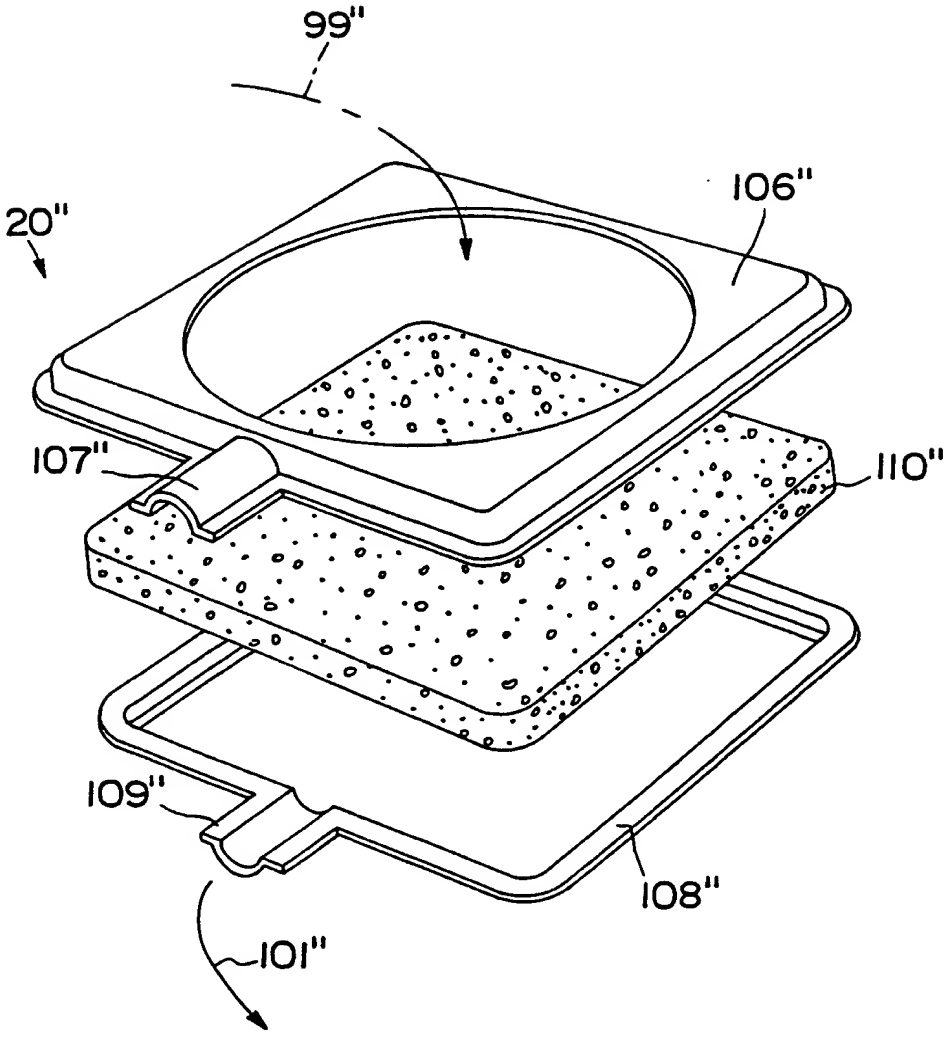


FIG. 14

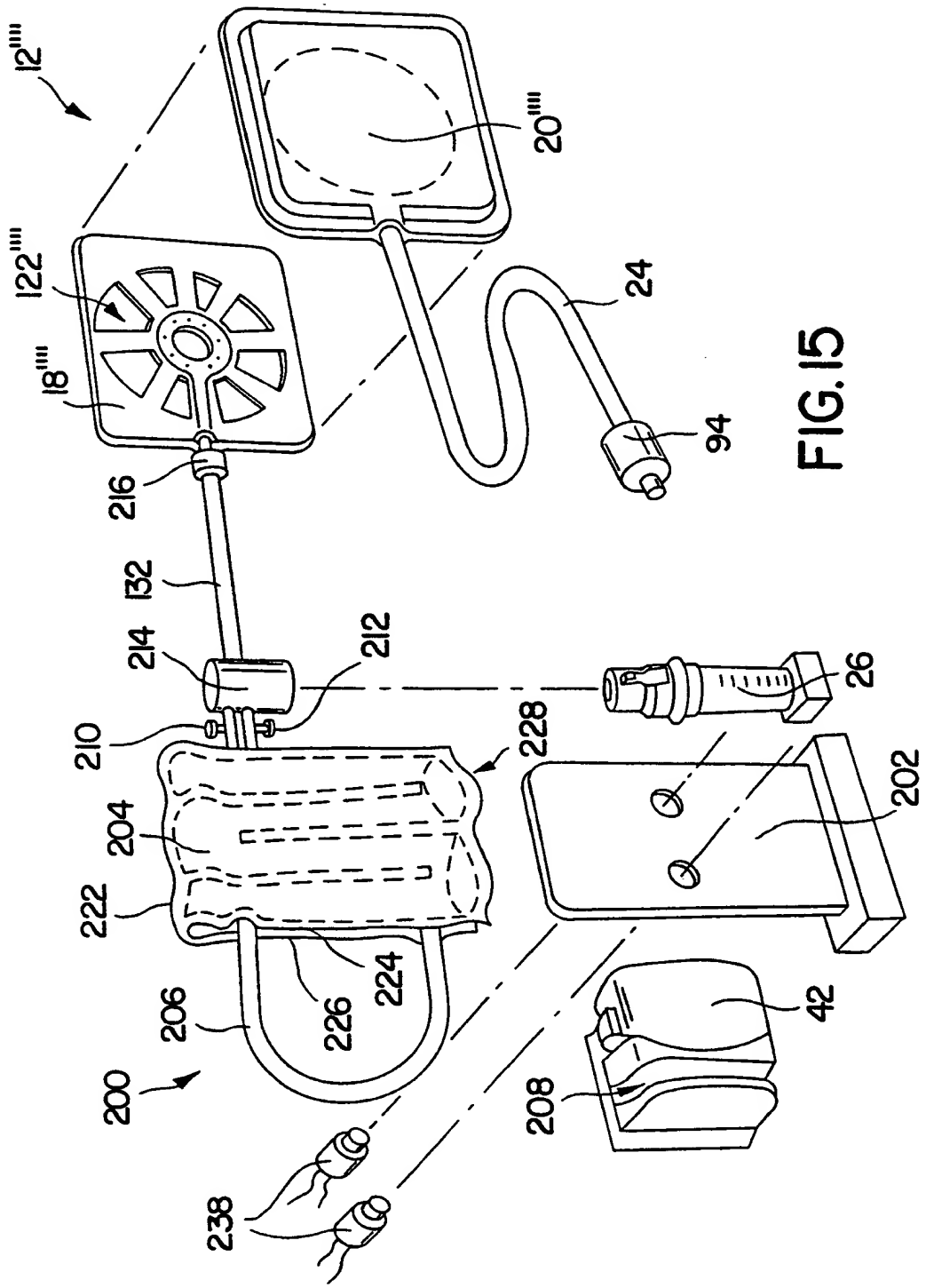

12''''
20''''
122''''
24
18''''
94
216
132
214
212
26
210
228
202
204
222
224
226
206
42
200
208
238

FIG. 15

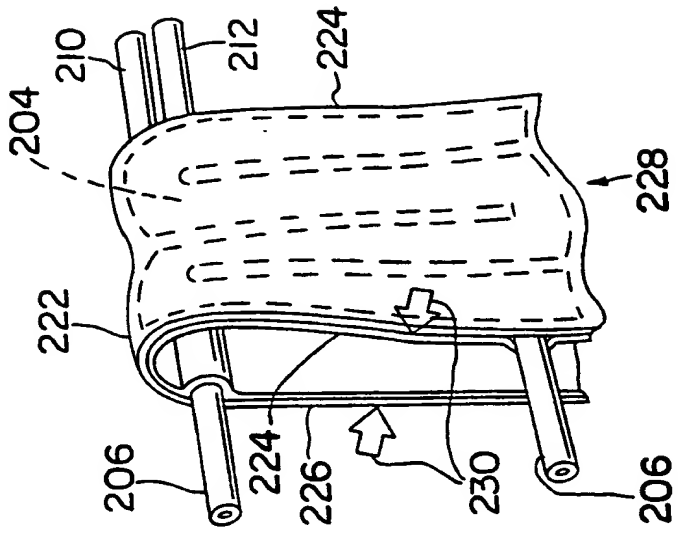

210
212
224
204
228
222
206
224
226
230
206

FIG. 17

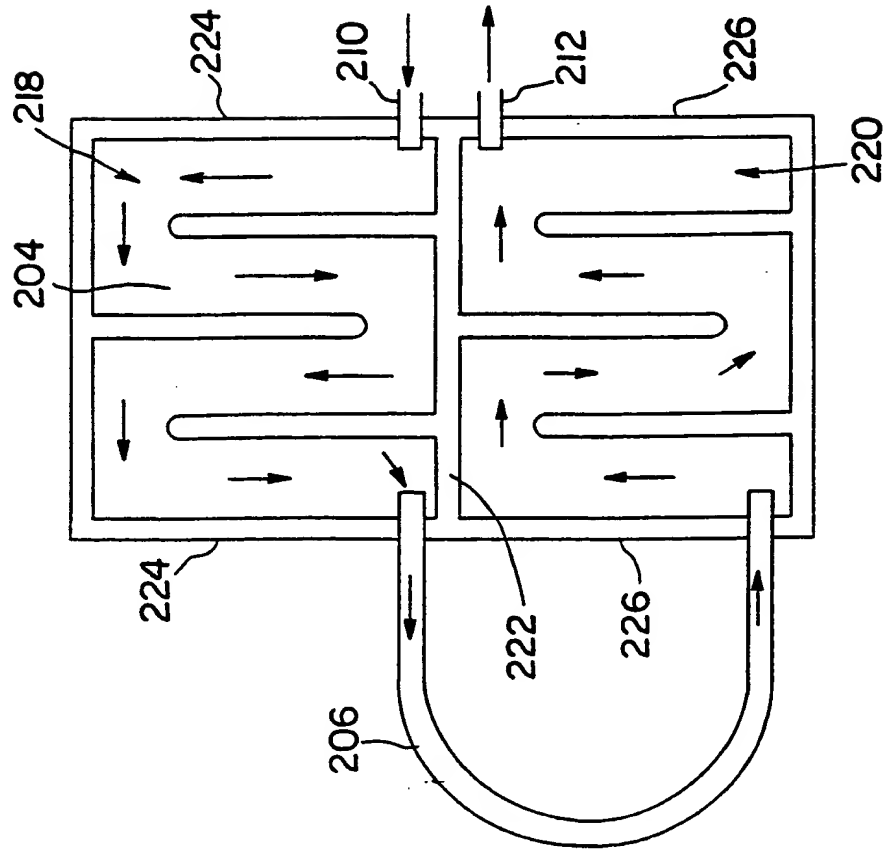

224
210
212
226
218
220
204
224
222
226
206

FIG. 16

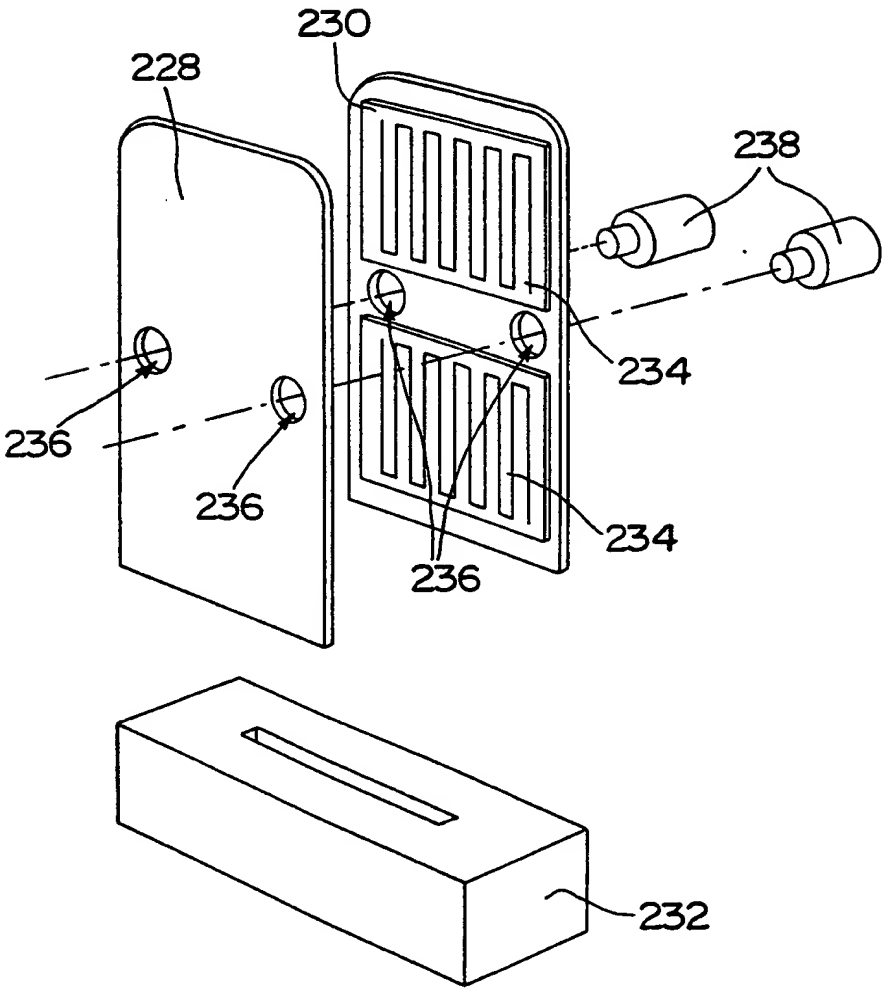


FIG. 18

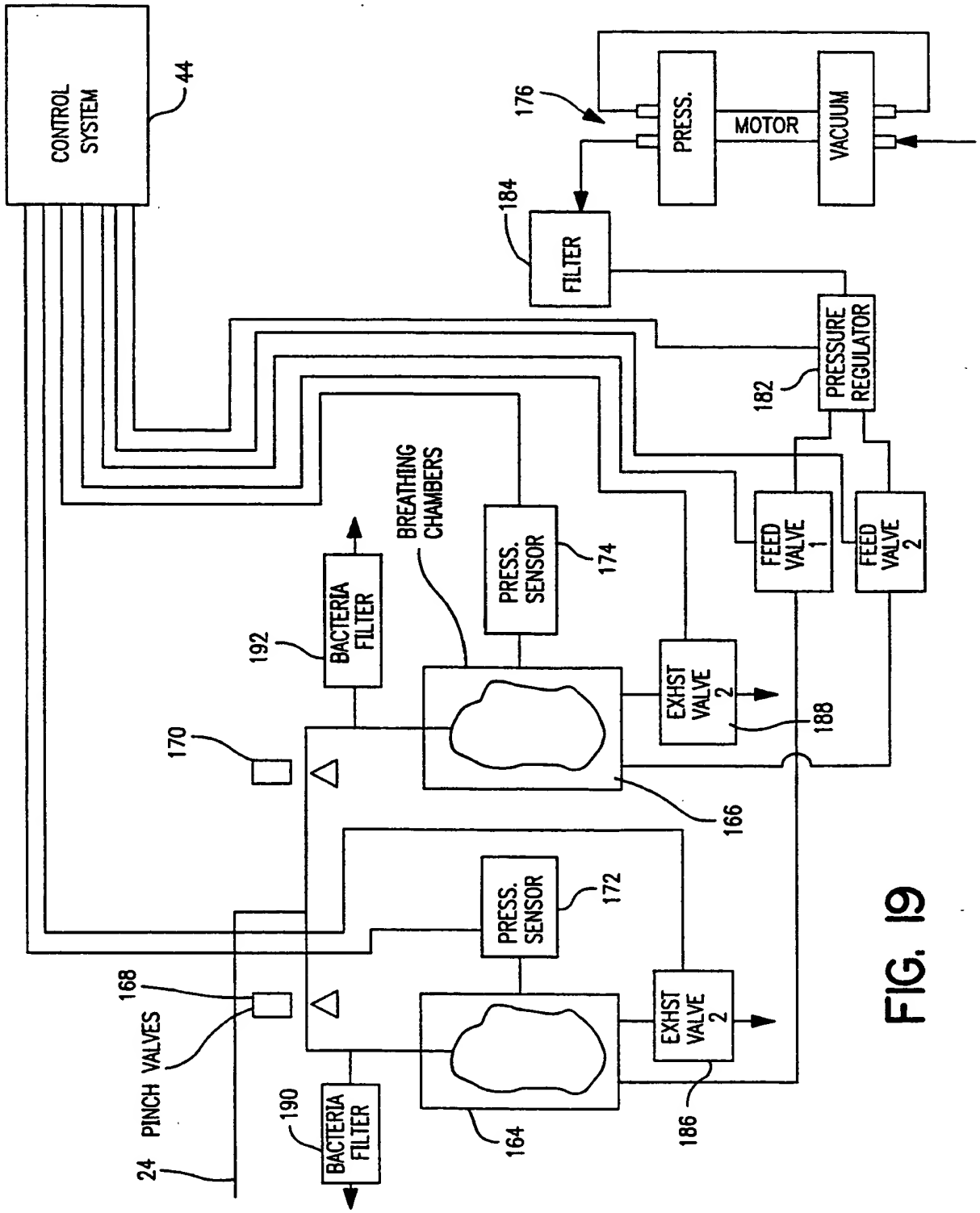

CONTROL SYSTEM
44
176
PRESS.
MOTOR
VACUUM
184
FILTER
PRESSURE REGULATOR
182
BREATHING CHAMBERS
PRESS. SENSOR
174
FEED VALVE 1
FEED VALVE 2
192
BACTERIA FILTER
EXHST VALVE 2
188
170
166
PRESS. SENSOR
172
168
PINCH VALVES
EXHST VALVE 2
190
BACTERIA FILTER
164
186
24

FIG. 19

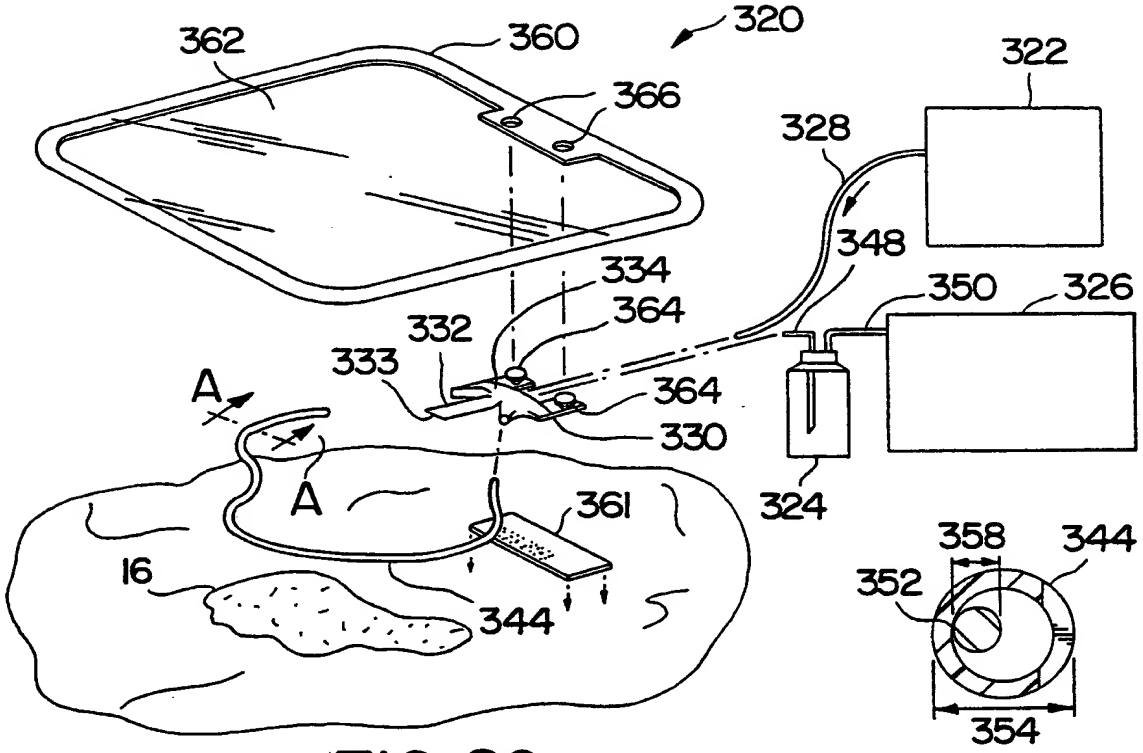


FIG. 20

FIG. 22

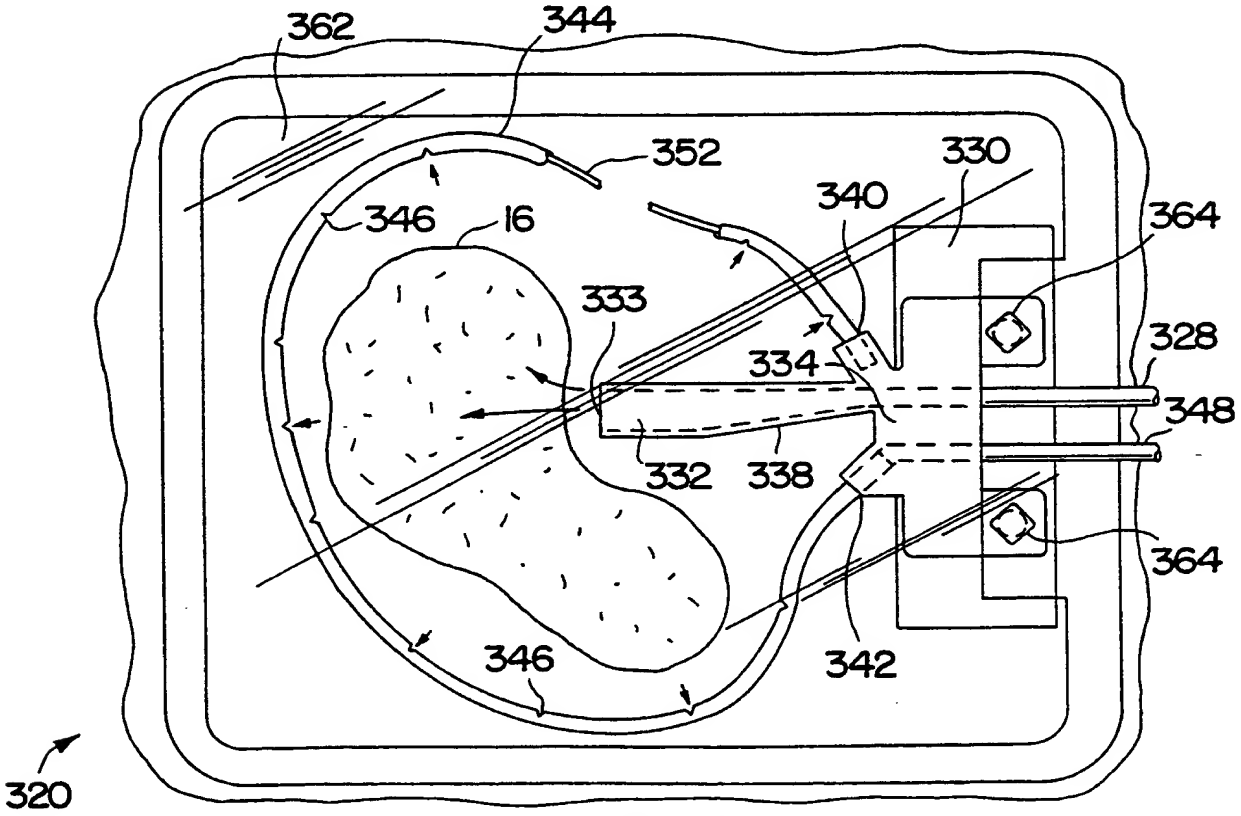


FIG. 21

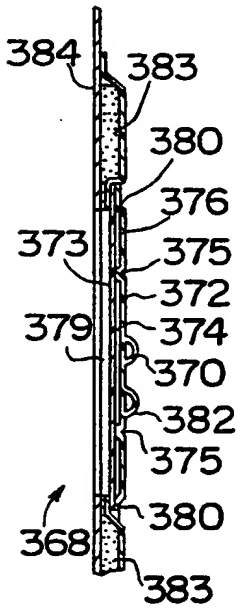


FIG. 24

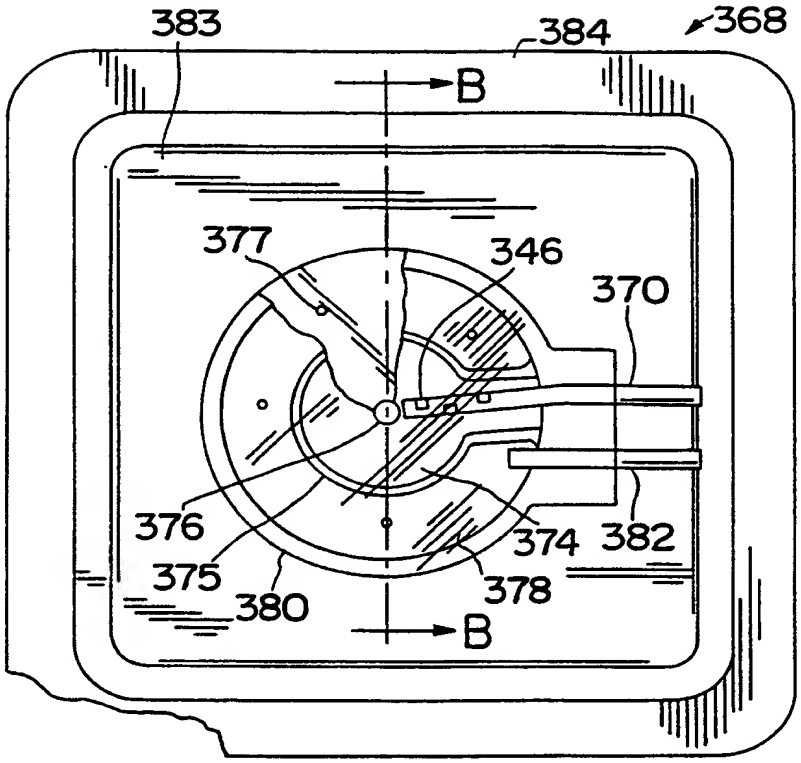


FIG. 23

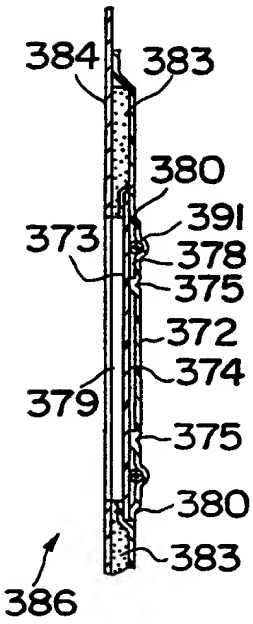


FIG. 26

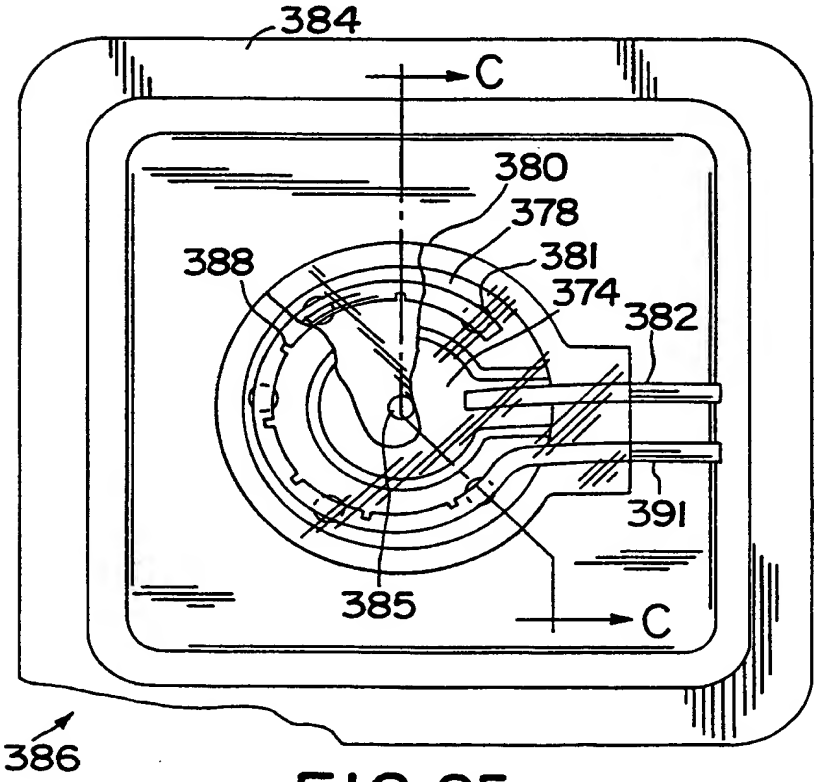


FIG. 25

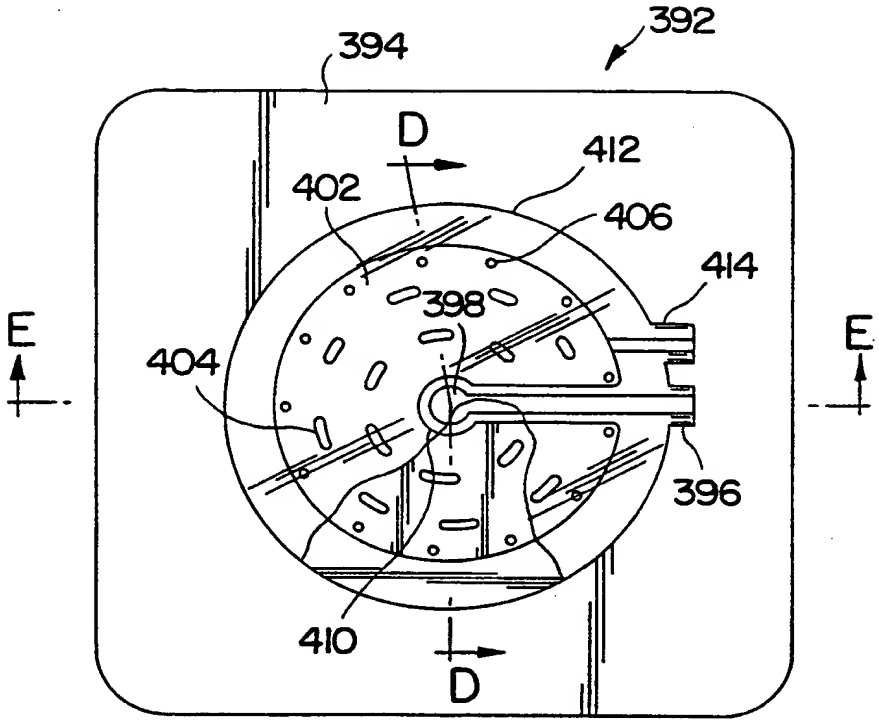


FIG. 27

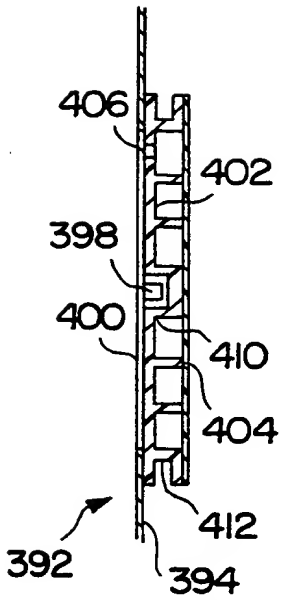


FIG. 28

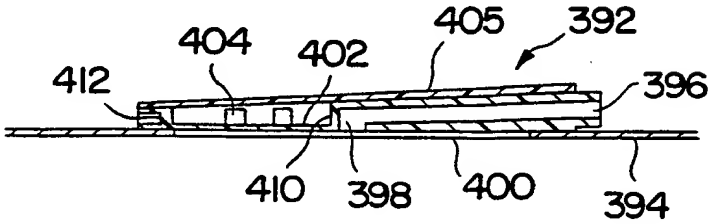


FIG. 29

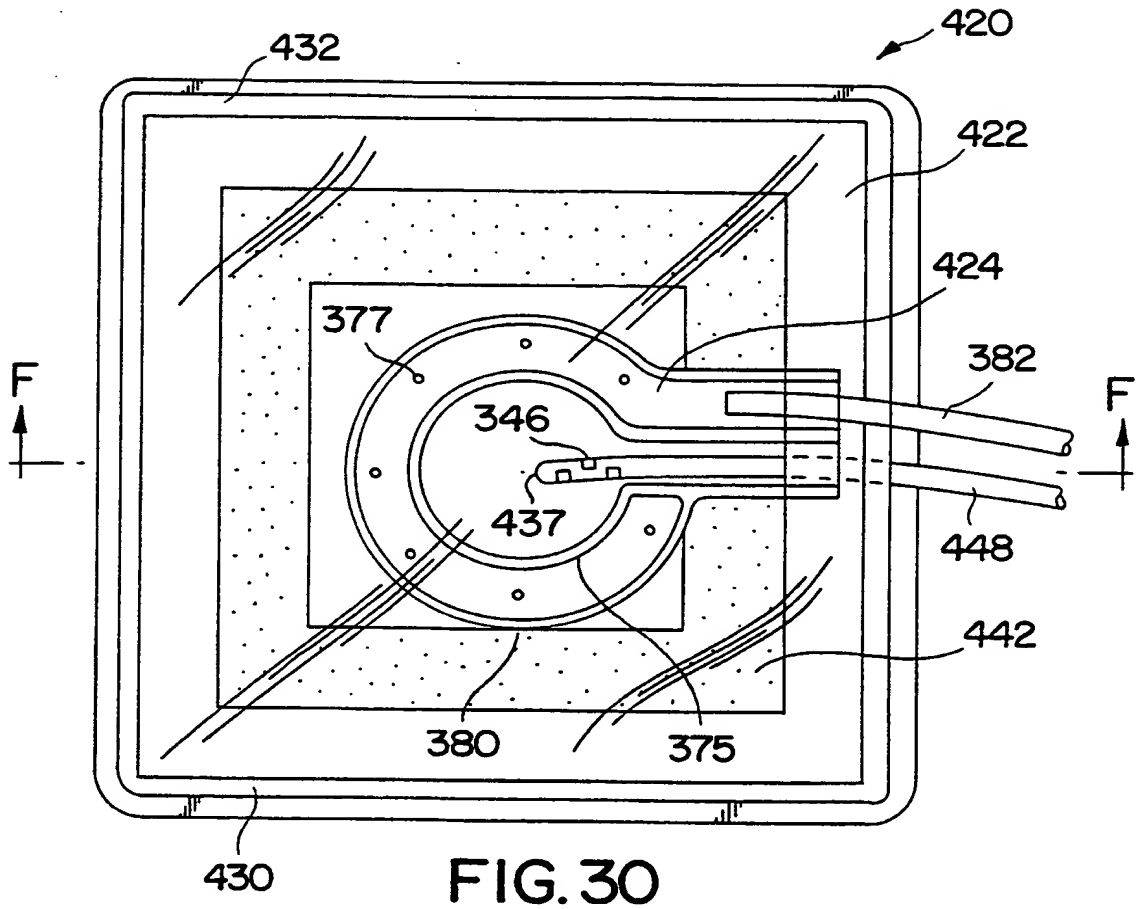

420
432
422
424
377
382
F
F
346
437
448
442
380
375
430

FIG. 30

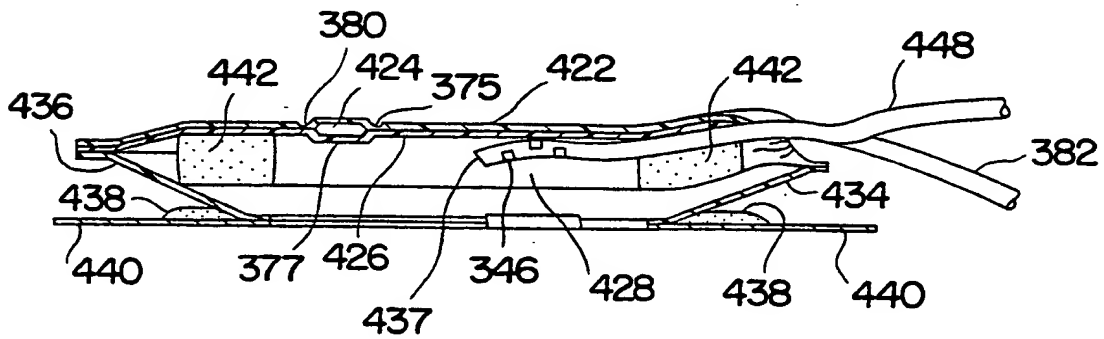

380
442
424
375
422
442
448
436
382
438
434
440
377
426
346
428
438
440
437

FIG. 31

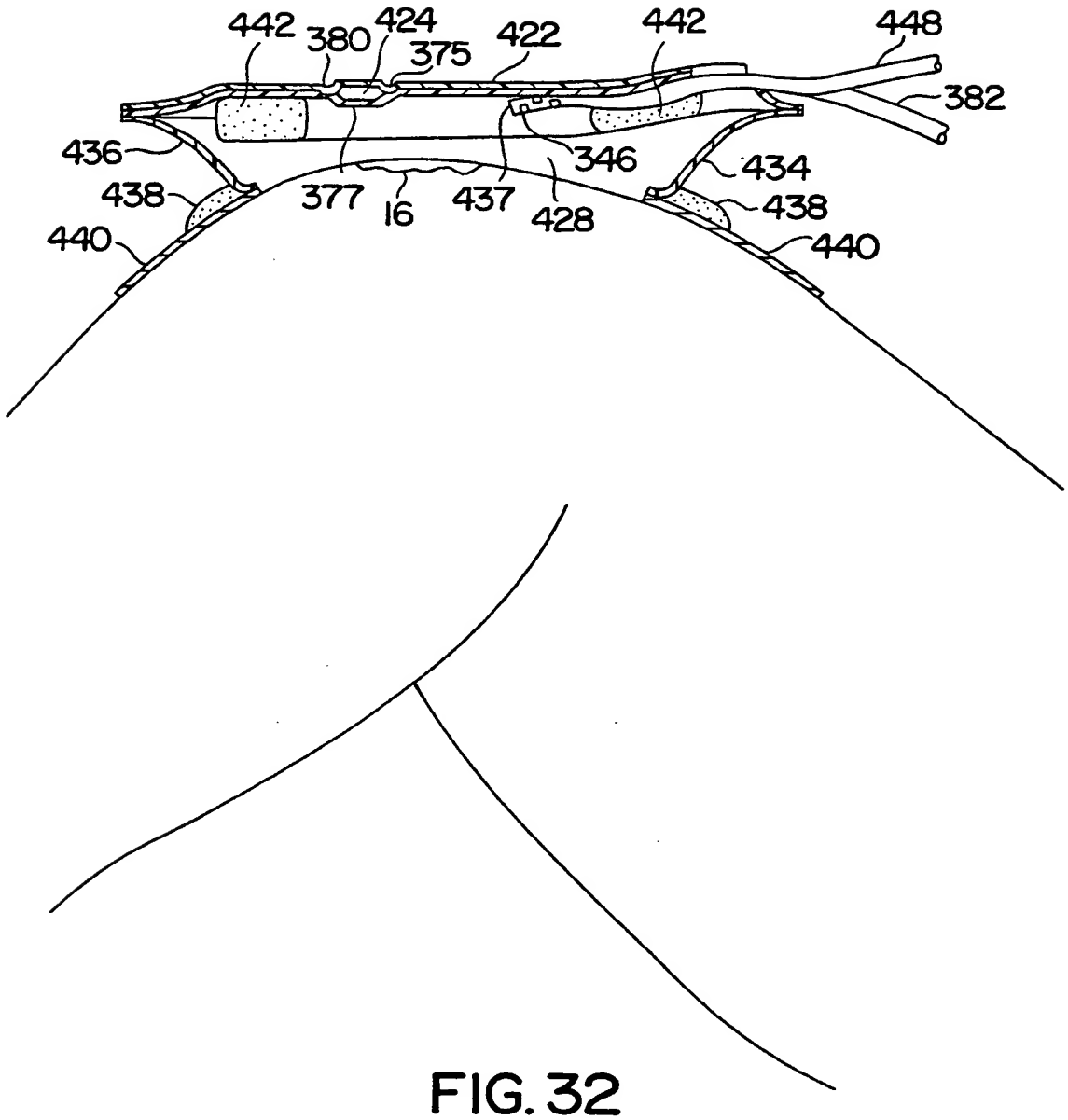

442
380
424
375
422
442
448
382
436
346
434
438
377
16
437
428
438
440
440

FIG. 32

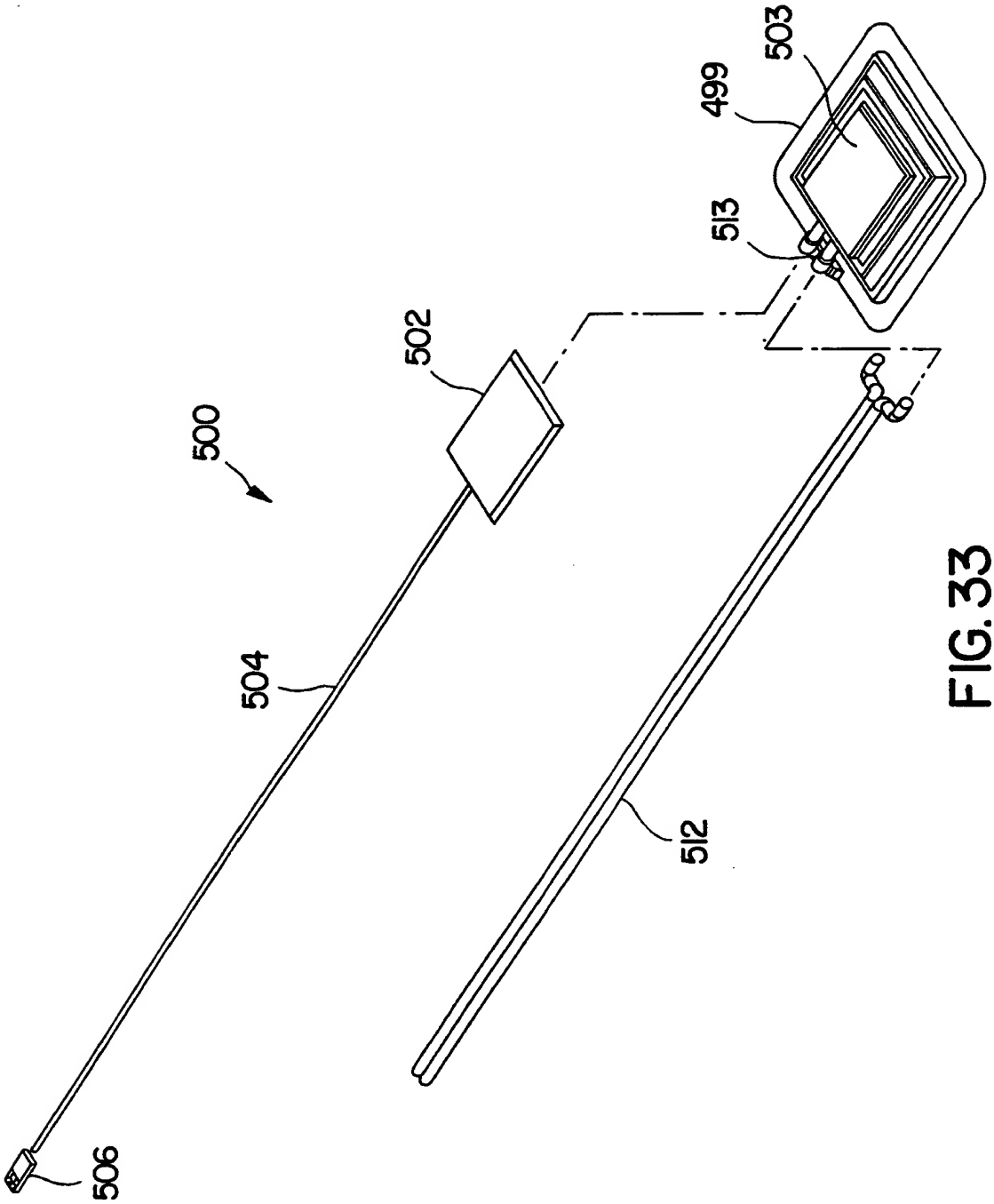


FIG. 33

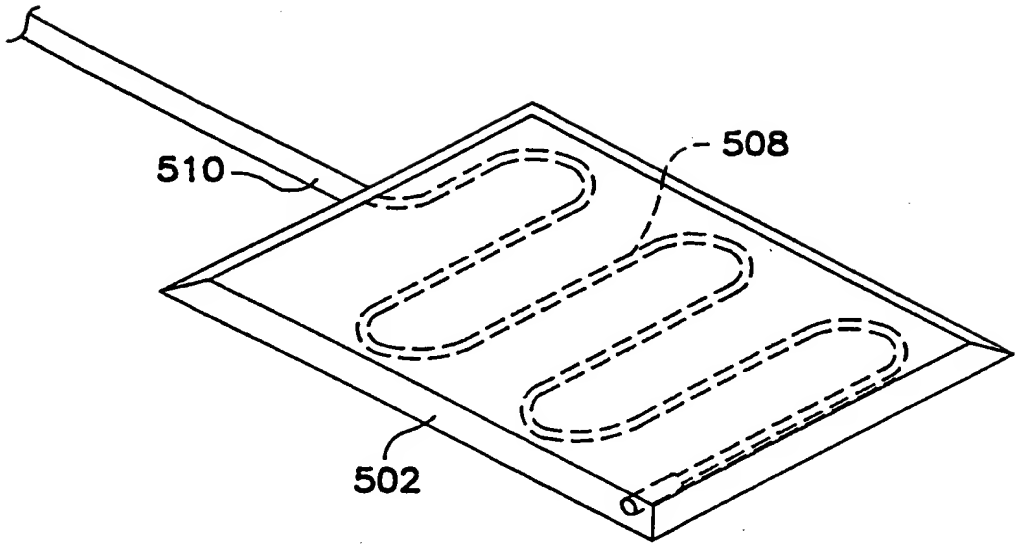


FIG. 34

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/17877

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 41 11 122 A (NEHER) 29 April 1993 (1993-04-29)	1-19
A	* THE WHOLE DOCUMENT *	20-42
X	GB 1 549 756 A (EVERETT ET AL.) 8 August 1979 (1979-08-08)	1
A	abstract; claims 1-6; figures 1-3	2-42
A	US 5 735 833 A (OLSON) 7 April 1998 (1998-04-07) abstract; figures 1-5	1-42
A	US 4 224 941 A (STIVALA) 30 September 1980 (1980-09-30) abstract; figures 1,2	1,9,10

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 October 1999	27/10/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Michels, N

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/17877

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 661 093 A (BECK ET AL.) 28 April 1987 (1987-04-28) ---	
A,P	EP 0 880 953 A (FLEISCHMANN) 2 December 1998 (1998-12-02) -----	

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/17877

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 4111122 A	29-04-1993	DE 3935818 A	02-05-1991
GB 1549756 A	08-08-1979	CA 1127488 A	13-07-1982
		DE 2809828 A	21-09-1978
		FR 2382900 A	06-10-1978
		JP 1338799 C	29-09-1986
		JP 53113188 A	03-10-1978
		JP 61001148 B	14-01-1986
US 5735833 A	07-04-1998	NONE	
US 4224941 A	30-09-1980	NONE	
US 4661093 A	28-04-1987	DE 3321151 A	13-12-1984
		AT 36242 T	15-08-1988
		DE 3473229 A	15-09-1988
		EP 0128388 A	19-12-1984
		JP 1709724 C	11-11-1992
		JP 3075184 B	29-11-1991
		JP 60007851 A	16-01-1985
		JP 1838924 C	25-04-1994
		JP 4261670 A	17-09-1992
		JP 5029469 B	30-04-1993
		US 4792328 A	20-12-1988
		US 4936834 A	26-06-1990
EP 0880953 A	02-12-1998	DE 19722075 C	01-10-1998
		DE 29715634 U	06-11-1997